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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff-Respondent, v. W. SCOTT HARKONEN, Defendant-Petitioner.	No. CR 08-00164 RS **UNITED STATES' OPPOSITION SEEKING DENIAL OF PETITION FOR WRIT OF ERROR CORAM NOBIS**

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INTRODUCTION

Dr. Harkonen is not entitled to coram nobis relief because he should have attacked his conviction earlier, and has failed to offer a sound reason for not doing so. All of the evidence that Dr. Harkonen relies on as support for his Petition was available to him before his sentencing. Dr. Harkonen filed two motions for a new trial before his sentencing, and yet chose not to raise an ineffective assistance of counsel claim in either motion.

Dr. Harkonen also could have raised his ineffective assistance of counsel claim in a § 2255 motion, while he was still in custody. Again, Dr. Harkonen knew the factual basis for his claim years ago. He sued the Kasowitz Firm for malpractice in 2011, yet did not file his Petition alleging ineffective assistance of counsel until July 30, 2014. Furthermore, Dr. Harkonen waited seven months to file his Petition, without offering a sound reason for not filing an ineffective assistance of counsel claim earlier as a § 2255 motion.

Even assuming arguendo that Dr. Harkonen's ineffective assistance of counsel claims are timely, Dr. Harkonen cannot prevail because he received effective assistance from a team of experienced attorneys from multiple firms. Furthermore, nothing alleged in his Petition undermines the result of Dr. Harkonen's trial.

Dr. Harkonen drafted a press release that falsely stated that the inconclusive results of a drug clinical trial conclusively proved that his company's drug helped patients with a fatal disease live longer. Shortly before and while Dr. Harkonen was drafting the press release, Dr. Harkonen was repeatedly told the clinical trial results were inconclusive. Dr. Harkonen hid the draft press release from everyone who understood the trial results and could have corrected his misrepresentations in the press release. As a result of his press release, Dr. Harkonen was charged with and convicted of wire fraud.

Before and during his trial, Dr. Harkonen was represented by a team of extremely experienced attorneys from multiple firms. His attorneys conducted an extensive nationwide search, over the course of more than a year, for biostatisticians, pulmonologists, and other potentially relevant expert witnesses. Because Dr. Harkonen's press release was false and misleading, it was difficult to find experts willing to support Dr. Harkonen's defense and testify that the press release

was accurate. Despite the difficulties they encountered, Dr. Harkonen's defense team retained a reasonable number of experts, including two biostatisticians, Dr. Lawrence Mayer and Dr. Patrick Hannon.

Going into trial, Dr. Harkonen's trial team adopted a reasonable strategy of calling Dr. Mayer as their principal biostatistician expert and to use Dr. Hannon, who had much less experience, as a possible rebuttal expert witness. Depending on how the trial went, they also considered calling other experts, including a pulmonologist.

Dr. Harkonen's trial lasted six weeks and included two biostatisticians, three medical doctors, an FDA regulatory expert, and 12 other witnesses, and over 200 exhibits. The trial involved complicated scientific issues including the statistical analysis of drug clinical trial results.

At trial, Dr. Harkonen's trial team elicited testimony through cross-examination of many of the government's witnesses, including expert witnesses, that was beneficial to Dr. Harkonen's defense. In particular, they were able to get InterMune's own Standford University trained biostatistician, Dr. Michael Crager, to admit that he approved and signed a drug patent application that contained statements very similar to Dr. Harkonen's press release. Based on this beneficial testimony, the four experienced attorneys representing Dr. Harkonen at trial agreed that defense expert testimony was unnecessary. Dr. Harkonen's trial team also concluded that not only did they not need any expert witness to raise reasonable doubt, but that there was a significant risk that cross-examination of the defense experts could harm Dr. Harkonen's defense. Nevertheless, the trial team thought that Dr. Mayer could, on balance, benefit Dr. Harkonen's defense by testifying the press release was accurate, and they intended to call him to do so. Dr. Harkonen's trial team based these decisions on their first-hand knowledge of the complicated evidence presented at Dr. Harkonen's six-week trial and the defense expert witnesses.

At the end of trial and on the eve of testifying, Dr. Mayer changed his opinion and stated for the first time that he thought the press release was misleading. Dr. Mayer's change of opinion was completely unforeseen by Dr. Harkonen's trial team. Dr. Harkonen's trial team had confirmed Dr. Mayer's opinion that the press release was accurate many times before and during trial. Dr. Mayer had not indicated that he would change his opinion about the press release until he did so on the eve

of testifying. Since Dr. Mayer would no longer testify that the press release was accurate, Dr. Harkonen's trial team reasonably decided not to call him as a witness.

Through his Petition, Dr. Harkonen is trying to second-guess his trial counsel's reasonable decision to forego calling expert witnesses who very well could have damaged his defense. Dr. Harkonen's trial team made a reasonable strategic decision to rest his defense on the beneficial testimony gained on the cross-examination of the government's witnesses, rather than risk damaging that defense by calling an expert witness. This decision was especially reasonable after Dr. Mayer changed his opinion on the accuracy of the press release. Given the complexity of Dr. Harkonen's trial and the risks posed by cross-examination of each defense expert witness, there is simply no way to conclude that the unanimous decision of Dr. Harkonen's trial team to forego calling defense expert witnesses was ineffective assistance of counsel.

Furthermore, it is sheer speculation to argue that the foregone defense expert testimony was more beneficial than harmful to Dr. Harkonen's defense, particularly when measured in the context of a complicated six-week trial. Dr. Harkonen's Petition fails to proffer any evidence that would have allowed the jury to find Dr. Harkonen's press release was accurate. Thus, even if Dr. Harkonen's trial counsel's decision not to seek defense expert testimony could be considered deficient, there is simply no way to determine whether any of those experts would have benefitted Dr. Harkonen's defense after cross-examination by the government.

By making prudent choices based on their experience and personal knowledge of the evidence and witnesses, Dr. Harkonen's trial team effectively represented Dr. Harkonen.

STATEMENT OF FACTS

I. Background on Dr. Harkonen's Press Release

A. Idiopathic Pulmonary Fibrosis ("IPF")

Pulmonary fibrosis is a disease in which an inflammatory process causes scarring of the lungs. Trial Transcript at 844. Pulmonary fibrosis is classified as idiopathic because the cause of the disease has not been determined. *Id.* The scar tissue eventually prevents the lungs from working,

resulting in slow suffocation. Doc.[1] 268 at 2. IPF is a fatal disease, and once the disease is diagnosed, the median survival of patients with the disease is three to five years. Trial Transcript at 845. IPF had no known cure at the times relevant to Dr. Harkonen's actions (and still has no cure today). *Id.* at 1473.

In the October 21, 1999 edition of the New England Journal of Medicine, Dr. Rolfe Ziesche *et al.* published the results of their study of 18 patients with IPF. Government Trial Exhibit 17. The Ziesche study was an open trial, meaning both the patients and researchers were aware which patients received which treatment. *Id.* at 1. Nine patients received a combination drug that included interferon gamma-1b, while the other nine patients received a combination drug without interferon gamma-1b. *Id.* Dr. Ziesche reported that all of the IPF patients who received interferon gamma had substantial improvement, compared to those patients who did not receive interferon gamma and had no such improvement. *Id.* However, both Dr. Ziesche, and the group of pulmonary experts who re-analyzed the results of the Ziesche study in 2000, noted that the Ziesche study was preliminary, *i.e.*, in no way proof that interferon gamma is effective in treating IPF, and that "[a] larger study is now required to determine whether our results can be confirmed." *Id.* at 5; *see also* Government Exhibit 19 at 17 ("[O]nly a well-designed phase III clinical trial would determine the potential efficacy of [interferon gamma] in the treatment of IPF.").

The re-analysis of the Ziesche study concluded that only 9 of the 18 patients definitely had IPF, and that 3 of the 18 patients definitely did not have IPF. *Id.* at 13-14. The reanalysis also noted "the treatment outcome was probably not clinically significant." *Id.* at 13.

B. Intermune and Actimmune

From February 1998 through approximately June 30, 2003, W. Scott Harkonen ("Dr. Harkonen") was the Chief Executive Officer ("CEO") of InterMune, a biopharmaceutical company that developed, marketed, and sold drugs for lung and liver diseases. Trial Transcript at 329-30. As CEO, Dr. Harkonen directed InterMune's operations, including research, marketing, and investor relations. Dr. Harkonen was also a member of InterMune's Board of Directors from February 1998

[1] Citations to the District Court docket for this case are abbreviated as "Doc."

through September 2003, and Chairman of the Board starting in January 2000. *Id.*

In 2000, sparked by the preliminary Ziesche study, InterMune embarked on a Phase III clinical trial of interferon gamma-1b (brand name, "Actimmune"), to determine whether Actimmune was effective in treating IPF. *See id.* at 392-93. InterMune planned to use the results, if favorable, to seek FDA approval for Actimmune to treat IPF and thereby increase its sales. *See id.* Actimmune was an expensive drug; in 2001-2002, the cost of Actimmune for one IPF patient for one year of treatment was $50,000 - $60,000. *Id.* at 1273, 2691; Government Trial 33 at 13. IPF patients were desperate for an effective treatment. Government Trial Exhibit 19 at 12 ("medical management of patients with IPF has been so unsuccessful"). Dr. Harkonen intended on taking advantage of a market lacking an IPF treatment. He stated during a July 2001 company-wide national sales meeting: "the market opportunity here is 2 and a half billion . . . . basically, it's simple math. . . . There is no reason we shouldn't capture 40% of this market and turn Actimmune into a billion dollar revenue producer." Government Trial Exhibit 34_3. In late 2000, InterMune started to hire sales representatives to focus on sales of Actimmune for IPF treatment. Trial Transcript at 2675-77; Government Trial Exhibit 33 at 27-30.

InterMune's revenue came almost entirely from Actimmune. Trial Transcript at 330. Although the United States Food and Drug Administration ("FDA") had approved Actimmune for the treatment of two rare pediatric diseases, Trial Transcript at 389-92, Actimmune's main market was for the fatal disease IPF. Doc. 268 at 2. In 2000, InterMune's sales were $11,201,000, comprised entirely of sales of Actimmune. Trial Transcript at 330. In 2001, InterMune's sales of Actimmune were $36,320,000, and its sales of all other drugs were $3,631,000. *Id.* In 2002, InterMune's sales of Actimmune were $105,802,000, and its sales of all other drugs were $6,163,000.[2] *Id.*

C. GIPF-001 Clinical Trial

In 2000, InterMune began a clinical trial, known as the GIPF-001 clinical trial, to see if

[2] In 2003, sales of Actimmune were $141,402,000, and sales of all other drugs were $12,736,000. Trial Transcript at 330.

Actimmune slowed the progression of IPF. Trial Transcript at 392-393. InterMune conducted the GIPF-001 clinical trial to obtain definitive proof that Actimmune helped IPF patients, which in turn, could be used to get FDA approval for Actimmune to treat IPF, and thereby increase sales of Actimmune. *Id.* The GIPF-001 results were inconclusive and failed to produce definitive proof of anything. Fleming Sentencing Declaration, Doc. 348 at ¶ 5 (hereafter "Fleming Decl.").

The GIPF-001 clinical trial was a Phase III clinical trial. Trial Transcript at 392-93. Phase III clinical trials are designed to provide definitive proof that a drug is safe and effective for a particular use. *Id.* at 354, 356. Because Phase III clinical trials are designed to provide definitive proof, they typically have a number of characteristics which increase the reliability of the trial's results. *Id.* at 354, 56-78. Phase III clinical trials are typically "placebo controlled," meaning some of the patients in the trial receive a fake drug. *Id.* at 361. This allows a comparison between the patients who took the real drug and the placebo patients to ensure that the drug helps patients do better than they would have done without the drug. *Id.* Phase III clinical trials like the GIPF-001 clinical trial are also typically "double blind," meaning neither the patients nor the doctors in the trial know whether the patient is getting the drug or a placebo until the trial is over. *Id.* at 361-62. Phase III clinical trials are conducted at different sites, with a principal investigator at each site. *Id.* at 357-58. The information gathered by the doctors during the clinical trial is sent to an independent contract research organization ("CRO"), which collects and analyzes the data. *Id.* at 357-58, 363-65. Because Phase III trials are blinded, only the CRO and certain safety monitors know the results of the trial before it ends. *Id.* at 363-65. At the end of the trial, the company conducting the trial will get the results. *Id.* at 364. Until the company decides to disclose the results, no one outside of the company, the CRO, and the safety monitors will know the results. *See id.* at 378-79.

Before starting a Phase III trial, whoever is conducting the trial must write a clinical trial protocol which describes how the trial is to be run, what the trial's objectives are, and how to analyze the data collected to see if those objectives have been met. *Id.* at 359, 370-71; Government Trial Exhibit 281. The Statistical Analysis Plan ("SAP") for a Phase III trial is the part of the clinical trial protocol that describes the trial's objectives or endpoints, and how to analyze the data to see if the endpoints have been met. Trial Transcript at 369. The SAP can be changed during the

clinical trial, but a final written protocol must be in place before the clinical trial's data are unblinded, that is, made available to anyone besides the CRO and safety monitors. *Id.* at 360-61, 371. Having a final SAP, governing the analysis of a clinical trial's data, in place before the data are unblinded is crucial for the integrity and reliability of a clinical trial. *Id.* at 369-72.

The principal objective that a clinical trial is designed to measure is called the primary efficacy endpoint, or primary endpoint. *Id.* at 372-376. There is typically only one primary endpoint per trial, and the trial is carefully designed to assess that endpoint. *Id.* A clinical trial may include other less important secondary endpoints. *Id.* at 374. Those secondary endpoints are ranked, beginning with the most informative and most likely to succeed. *Id.* at 377. A third category, tertiary or exploratory endpoints, are given less weight and are not intended as a basis for drawing any firm conclusions. *Id.* at 374.

By pre-specifying what the clinical trial is intended to measure and how it will be measured, researchers preclude themselves from manipulating the data in search of favorable results. *Id.* at 371. As Dr. Marc Walton of the FDA testified, "[i]t's well-understood if one can look at the data and then pick out which parts of the data we would like to analyze and in which way, we can always find something in the data that will look positive." *Id.*

InterMune wrote an SAP for the GIPF-001 clinical trial in 2000, and amended it several times before the end of data collection on June 26, 2002. Government Trial Exhibits 274-81. The SAP listed progression-free survival or patients living without any worsening of their lung capacity as the primary endpoint. *Id.* Progression of IPF was defined as either a specific, measurable decrease in Forced Vital Capacity ("FVC") (a measure of lung function), a specific, measurable increase in the A-a gradient (another measure of lung function), or the death of the patient. *Id.* In its final form, the SAP identified nine secondary endpoints, listed in order of clinical relevance, and eight tertiary endpoints. *Id.* In addition, the SAP strictly defined how the data would be analyzed to determine whether each endpoint had been met. Trial Transcript at 662-67, 2187-88. Significantly, the SAP did not allow for analyzing the data by subgroups based upon the patients' FVC. *Id.* at 665.

The seventh-ranked secondary endpoint for the clinical trial was survival, also referred to as mortality (i.e., patients not dying while taking the medicine). Government Trial Exhibits 274-81.

Survival was ranked seventh in part because of concerns that there would not be enough deaths for a meaningful statistical analysis of survival. Trial Transcript at 666-67. Meaningful statistical analysis requires sufficient data to allow for reliable analysis. The GIPF-001 clinical trial was approximately a two-year trial. *Id.* at 665. Researchers involved in the GIPF-001 clinical trial felt that there would not be enough deaths in just two years to permit a reliable analysis of survival in the trial. *Id.* at 667, 1350, 2195.

The GIPF-001 clinical trial involved 330 patients – 162 treated with Actimmune, 168 receiving a placebo – located at 58 separate facilities throughout the United States and Europe. Government Trial Exhibit 1. Dr. Ganesh Raghu, a board certified pulmonologist, was the Chair of the Steering Committee responsible for the design of the GIPF-001 clinical trial; Dr. Raghu was also a principal investigator for the trial. Trial Transcript at 862-63, 865-66. The Data Monitoring Committee ("DMC") for the GIPF-001 clinical trial was an external group of scientists whose principal role was to safeguard the interests of patients who were enrolled in the clinical trial. *Id.* at 653-55. As the safety monitors, the DMC was unblinded during the trial and reviewed the data as it came in for safety. *See id.* at 657-58.

Professor Thomas Fleming chaired the DMC. *Id.* at 653-54. Dr. Fleming received his Ph.D. in statistics from the University of Maryland in 1976, had worked for seven years at the Mayo Clinic as a consultant in the Department of Epidemiology and Statistics, and had been a professor of biostatistics at the University of Washington in Seattle for 25 years. *Id.* at 644-53. Dr. Fleming testified that he had overseen more than 200 clinical trials, and that he had published more than 200 articles and several books about biostatistics. *Id.* at 648-51. The DMC monitored the GIPF-001 clinical trial, and how the data were collected regarding the safety and efficacy of Actimmune. *Id.* at 653-58.

D. GIPF-001 Clinical Trial Results

According to the terms of the SAP for the GIPF-001 clinical trial, the trial was a complete failure. Trial Transcript at 372-74, 600-05, 638. The results of the GIPF-001 clinical trial met none of the definitions of success in the SAP for the trial's primary endpoint and nine secondary endpoints. *Id.* at 599-600, 620.

Generally, the significance of primary endpoint results is expressed through a p-value, which is a number between 1 and 0. *Id.* at 674. The lower the p-value, the greater the probability the result reflected by the data is meaningful, and not due to chance, that is, a random result with no meaning. *Id.* at 674-76. For example, a primary endpoint with a p-value of 0.05 indicates that the data obtained in the trial would occur by chance less than 5% of the time. *Id.* at 675-76. Generally, if the p-value for the primary endpoint is equal to or less than 0.05, then the results on the primary endpoint are considered statistically significant and have meaning; if the p-value for the primary endpoint is greater than 0.05, the results are generally considered unreliable and not statistically significant. *Id.* at 374, 674-76. The SAP for the GIPF-001 clinical trial used the 0.05 p-value as its measure of statistical significance for its endpoints. *See* Government Trial Exhibit 282 at 9.

A p-value can be calculated for all the results of a study, including its secondary endpoints, tertiary endpoints, and even endpoints determined through post hoc analyses – that is, analyses that are not in the SAP and are done only after the data have been revealed. Trial Transcript at 674-84. However, to properly interpret a p-value, it is necessary to understand the context in which each p-value was generated. *Id.* at 676. Specifically, in order to understand a particular p-value, one needs to know, among other things: (1) how many endpoints there are, because the more secondary and tertiary endpoints there are, the less statistically reliable the results for any one endpoint are likely to be ("the multiplicity effect"); (2) whether the primary endpoint has failed, because secondary endpoints are dependent on the primary endpoint achieving statistical significance; and (3) whether the analysis was pre-specified. *Id.* at 676-79. Accordingly, a p-value below 0.05 for a secondary, tertiary, or post-hoc endpoint may not be statistically significant, depending on context. *Id.* In particular, if the primary endpoint has failed – that is, its p-value is larger than 0.05 – then as a general matter, no definitive conclusions can be drawn from other analyses arising out of that clinical trial, including even secondary endpoints that have a p-value lower than 0.05. *Id.* at 375-77, 678-79, 2188

For the GIPF-001 clinical trial, the p-value for the primary endpoint, progression-free survival time, was 0.52 – far too high to demonstrate any statistically significant correlation between Actimmune and progression-free survival. *Id.* at 826; *see also id.* at 477, 685, 687, 2201-02. Dr.

Fleming explained the 0.52 p-value on the primary endpoint of the GIPF-001 clinical trial as meaning: "that you would have seen a bigger difference by chance alone more than half the time. … These results were entirely consistent with no effect." *Id.* at 685. None of the secondary endpoints achieved a p-value below 0.05. *Id*. Explaining the results and p-values on the secondary endpoints, Dr. Fleming testified that "there was quite a strongly reinforced insight …the trial had not provided evidence that Actimmune provides a clinically meaningful effect." *Id*. at 685-86. Because none of the endpoints achieved a p-value of 0.05 or lower, they all failed according to the terms of the SAP. *Id.* at 372-74, 600-05, 638; Government Trial Exhibit 282 at 9.

Survival, the seventh of the nine secondary endpoints in the GIPF-001 clinical trial had a p-value of 0.084. Trial Transcript at 2201-02. While this p-value "didn't meet the standard of even a primary test of significance," it represented "a trend in the survival data that appeared to show a benefit." *Id.* However, the strength of the 0.084 p-value of the survival endpoint of the GIPF-001 clinical trial must be put into context. *Id.* at 676, 697. A secondary endpoint in a clinical trial is dependent upon the primary endpoint of a clinical trial achieving statistical significance, which did not occur in the GIPF-001 clinical trial. *Id.* at 678-79. Further, because of the multiplicity effect, the p-value of 0.084 for survival is less statistically reliable because survival was one of nine secondary endpoints in the GIPF-001 clinical trial. *Id.* at 679. Survival was ranked seventh out of nine secondary endpoints, because, based on the number of patients participating in the GIPF-001 clinical trial, InterMune did not believe there would "be enough deaths during the course of this study" to show a survival effect. *Id.* at 1350.

Additionally, the GIPF-001 clinical trial showed no improvement in lung function for patients taking Actimmune. *Id.* at 698. "The measure that was used for the primary endpoint was a lung function measure.… So it's particularly problematic if you're suggesting that a trend on survival is real when the mechanism through which you might have thought you would have achieved that trend[, improved lung function,] is not showing an effect." *Id.* Without an improvement in lung function, there was even more uncertainty that the survival trend was real. *Id.* at 699.

E. Post-Hoc Analysis

On August 16, 2002, Dr. Michael Crager, InterMune's Chief Biostatistician, received the results from the GIPF-001 clinical trial, learning that the primary endpoint and all nine secondary endpoints had failed. Trial Transcript at 2201-02. As Dr. Fleming testified, "these results were entirely consistent with [Actimmune having] no effect." *Id.* at 685. On or around August 16, 2002, Dr. Harkonen called Stephen Rosenfield, InterMune's general counsel, to tell him "that the data really wasn't looking very good." *Id.* at 3087-88. By InterMune's own internal criteria, this was the worst of the possible outcomes they had anticipated. *Id.* at 2719-23.

In looking at the results, Dr. Crager noticed a "trend" in the results suggesting a survival benefit, the seventh of the secondary endpoints, but concluded the finding was not statistically significant. *Id.* at 2201-02. Dr. Crager reported this to Dr. Harkonen and Dr. Jim Pennington, InterMune's Executive Vice President of Medical and Scientific Affairs, telling them that there was "no evidence of an effect on the primary efficacy endpoint, but that there was a trend in the survival data" which, he concluded, might serve as the basis for a trial with survival as the primary endpoint. *Id.* at 2204. However, Dr. Crager expressed his concern to Dr. Harkonen and Dr. Pennington that there was "no apparent way" that Actimmune could result in a survival benefit given that: (1) the lung function tests that were part of the primary endpoint indicated no apparent effect on lung function; and (2) no evidence from the trial explained how the drug might help IPF patients live longer. *Id.* at 2203, 2218-19.

On August 17, 2002, on his own initiative, Dr. Crager contacted Pharmanet, the CRO involved in collecting data for the trial, and asked it to analyze the survival time for subgroups of patients with FVCs greater than and less than 60%. *Id.* at 2205-07. Companies can do post-hoc analyses, i.e., post-trial analyses of data that are not pre-specified in the trial protocol. *Id.* at 385-86. However, p-values for post-hoc subgroup analyses are "very hard to interpret," even when very low. *Id.* at 2240.

Dr. Crager received the subgroup results on August 21, 2002 and shared them with Dr. Harkonen and Dr. Pennington. *Id.* at 2209-11. Dr. Harkonen then directed Dr. Crager to conduct additional post-hoc subgroup analyses of mortality by breaking the patients into subgroups of mild

(FVC 71-100%), moderate (FVC 56-70%), and severe (FVC 0-55%) IPF patients. *Id.* Nowhere in the trial's SAP had these subgroups been identified or proposed as a basis for analyzing the mortality data. *Id.* at 2206.

Dr. Crager received the results from this second post-hoc subgroup analysis on August 22, 2002, and shared them with Dr. Harkonen. *Id.* at 2212-13. Dr. Harkonen then told Dr. Crager to run the data again, this time for two subgroups, those with FVC greater than and less than 55%, thus combining the mild and moderate IPF sufferers into one group. *Id.* Dr. Harkonen's idea was to choose the parameters so as to "focus[] on that patient population that had the best outcome in terms of mortality." *Id.* at 2736. Dr. Harkonen "indicated that they were going to have Michael Crager cut that data and slice it until they got the kind of results they were looking for." *Id.*

Dr. Crager ran those analyses, and again shared the results with Dr. Harkonen. *Id.* at 2216. In this manipulation of the data, only 6 of the 126 patients treated with Actimmune in the so-called "mild to moderate group" died during the clinical trial, compared to 21 of the 128 patients in the corresponding placebo group, a result that represented a greater than 70% reduction in mortality, yielding a p-value of 0.004. Doc. 268 at 12-13. However, despite this low p-value, no definitive conclusions could be made regarding Actimmune's efficacy for treating patients with IPF because the primary endpoint failed, and this p-value of 0.004 was achieved as a result of a retrospective analysis of a subgroup that was not identified as part of the SAP. Trial Transcript at 2188-89.

F. Dr. Harkonen Drafts Press Release

Despite the failed results on the primary and all secondary endpoints of the GIPF-001 clinical trial, and the ambiguous data on the survival of the trial patients, Dr. Harkonen wrote and issued a press release claiming the GIPF-001 results demonstrated that Actimmune had a survival benefit for IPF patients, and which included as part of its headline that Actimmune: "Reduces Mortality by 70% in Patients with Mild to Moderate Disease." Government Trial Exhibit 1; Fleming Decl. at ¶¶ 5-7, 9.

Weeks earlier, while awaiting the results of the GIPF-001 clinical trial, InterMune began planning a press release to announce those results. Trial Transcript at 2560. This press release was, according to Rosenfield, the most important in the company's history. *Id.* at 3285-86, 3366. The

"key target audience" for the press release was patients, doctors, caregivers, and patient family members. *Id.* at 2567; Government Trial Exhibit 14. Dr. Harkonen knew about and approved plans to disseminate the press release to doctors and patients, among many others, as part of InterMune's sales and marketing strategy. Trial Transcript at 1082-84, 1086, 1088-93, 2725-27, 2750, 2752, 2802, Government Trial Exhibit 4.

Dr. Harkonen worked with James Weiss, the owner of Weisscomm, a communications consulting firm, to draft the press release. Trial Transcript at 2552-53. Weiss specialized in corporate communications and public relations, and was not a doctor or a statistician. *Id.* Weiss's main information about the GIPF-001 clinical trial results came from Dr. Harkonen, who informed Weiss that the trial results were generally positive in terms of showing some survival benefit, although the primary endpoint had not been met. *Id.* at 2562-63, 2577. In the past, Weiss had had access both to the raw data and to InterMune's medical staff when working on pharmaceutical-related InterMune press releases. *Id.* at 1385, 2576-77. This time, although Weiss asked Dr. Harkonen for access to both, he got neither. *Id.* at 2576-78, 2580-81.

Weiss began working on drafts of the press release for Dr. Harkonen at least as early as August 22, 2002, at which time he did not have any access to the GIPF-001 clinical trial data. *Id.* at 2561; Government Trial Exhibit 45. Dr. Harkonen and Weiss began trading drafts on August 25, 2002, and worked on the press release until it was completed on August 27, 2002. Government Trial Exhibits 13-14. Weiss had a draft version of the press release which contained a quote that the press release would attribute to Dr. Raghu. Trial Transcript at 2579, 2589. As late as August 27, 2002, the day the press release was completed, Weiss had not identified and was unaware which doctor would be quoted in the press release. *Id.* at 2579. Based on his work on prior press releases at InterMune, Weiss believed the draft press release would be circulated among "people from medical, clinical affairs, and stat[istic]s." *Id.* at 2581. However, Dr. Harkonen was the only person with a medical, clinical, or regulatory background at InterMune who provided input in drafting the press release prior to the press release being finalized on August 27, 2002, and issued on August 28, 2002. *Id.* at 2577-78. As noted above, the press release claimed that the results of the GIPF-001 trial "demonstrate[d]" that Actimmune had a survival benefit for IPF patients. Government Trial

Exhibit 1.

G. Press Release is False and Misleading

The underlying numbers resulting from the GIPF-001 clinical trial were not in dispute: the results of the trial were inconclusive. Fleming Decl. at ¶¶ 4-7, 9. Although the GIPF-001 clinical trial results showed a possible survival benefit, that survival benefit was also inconclusive, and the data were not reliable enough to draw any definitive conclusions that Actimmune had a survival benefit for IPF patients. *Id.*; Trial Transcript at 2201-02. Despite this, the August 28, 2002 press release falsely and misleadingly represented that the GIPF-001 clinical trial results alone proved Actimmune had a statistically significant survival benefit for IPF patients. Government Trial Exhibit 1.

All prespecified endpoints for the GIPF-001 clinical trial failed. Trial Transcript at 599-600, 620. Additionally, the GIPF-001 clinical trial showed that Actimmune produced no physiological effect, meaning patients taking Actimmune had no improvement in lung function. *Id.* at 698; *id.* (". . . [T]he measure that was used for the primary endpoint was a lung function measure."). The lack of improvement in lung function increased the uncertainty of the possible survival trend in the results. *Id.* at 699.

The statistically significant survival benefit presented in the press release was the result of post-hoc analyses, which "are typically very unreliable." *Id.* at 683-84. While the press release correctly stated that the primary endpoint was not met, the only p-values it provided were 0.084 and 0.004, which were misleading because the press release did not provide a proper context for those p-values. Government Trial Exhibit 1.

The press release did not state that the clinical trial missed all nine of its secondary endpoints, although on the second page, it did give a p-value of 0.084 for the secondary endpoint of survival, which was the best of the p-values for the secondary endpoints. Government Trial Exhibit 1. By failing to specify that survival was one of nine secondary endpoints, and to provide proper context regarding the multiplicity effect of multiple endpoints, the press release made the 0.084 p-value look more reliable than it really was. *Id.*; Trial Transcript at 695-96.

The headline of the press release stated: "InterMune Announces Phase III Data

Demonstrating Survival Benefit of Actimmune in IPF - Reduces Mortality by 70% in Patients with Mild to Moderate Disease." Government Trial Exhibit 1. The press release stated: "Actimmune also demonstrated . . . a statistically significant survival benefit in patients with mild to moderate IPF," with a p-value of 0.004, without stating that this subgroup was not a primary, secondary, or even a pre-specified exploratory endpoint for the trial. *Id.* The press release did not mention that the mild-to-moderate IPF patient analyses upon which the statements in the press release were based were post-hoc analyses and not part of the SAP for the GIPF-001 clinical trial. *Id.* The press release also stated that the data "confirm[ed] the survival benefit seen" in the Ziesche trial. *Id.*

The press release stated that "[t]here was also approximately a 10% relative reduction in the rate of progression-free survival associated with Actimmune versus placebo, the trial's primary endpoint, but this was not a statistically significant difference." *Id.* The p-value for the primary endpoint was 0.52, nowhere close to statistical significance. Trial Transcript at 685, 692-93. The section describing the clinical trial details included a similar statement, but then immediately noted that "[i]mportantly, Actimmune also demonstrated a strong positive trend in increased survival in the overall patient population, and a statistically significant survival benefit in patients with mild to moderate IPF." Government Trial Exhibit 1.

Finally, by choosing to include only the most preferable post-hoc analysis in the press release, the press release was misleading. *Id.* While the press release notes a reduction in mortality for patients with mild-to-moderate disease, there is no mention that in the more severe patients, there was "an observed higher death rate [for patients] on Actimmune compared to [patients on placebo]." Trial Transcript at 702.

Overall, the GIPF-001 clinical trial results were inconclusive. Fleming Decl. at ¶¶ 5-7, 9. The press release used the best data from the trial and post-hoc analyses, and presented that data out of context to falsely state that the GIPF-001 clinical trial results showed Actimmune had a statistically significant survival benefit for IPF patients. Trial Transcript at 684, 695-97, 703-706; Government Trial Exhibit 1.

H. Evidence of Dr. Harkonen's Intent to Defraud

Dr. Harkonen's actions throughout the drafting, issuance, and aftermath of his press release

were evidence that he knew the statements in the press release were fraudulent and had an intent to defraud or mislead. *See infra* Facts Section I.H.1.-7.[3]

1. Faxing of some, but not all post-hoc subgroup analyses to FDA

At Dr. Harkonen's direction, some, but not all of the post-hoc sub-group analyses were faxed to the FDA on August 22, 2002. Trial Transcript at 2217-21. The fax included only the sub-group analysis using the 60% cutoff. *Id.* at 2219-20. The fax did not include the other post-hoc FVC analyses. *Id.* Dr. Harkonen told Dr. Crager not to send all of the post-hoc analyses to the FDA "because we didn't want to make it look like we were doing repeated analyses looking for a better result." *Id.* at 2220-21.

2. Dr. Harkonen is Warned that Survival Benefit in GIPF-001 Clinical Trial Results is Unreliable

Dr. Harkonen was warned several times that the GIPF-001 clinical trial had failed and that the possible survival benefit seen in the data was unreliable and inconclusive. Trial Transcript at 472-77, *see also id.* at 683-84.

On August 16, 2002, Dr. Crager reported to Dr. Harkonen that the trial showed "no evidence of an effect on the primary efficacy endpoint, but that there was a trend in the survival data. And that we might want to follow up and do another trial." *Id.* at 2204. Crager recommended doing another Phase III clinical trial to test whether the possible survival benefit in the GIPF-001 clinical trial data was real. *Id.*

On August 19, 2002, Dr. Harkonen and InterMune management met with the DMC, including Dr. Fleming, to discuss the results. *Id.* at 684. Dr. Fleming told Dr. Harkonen that the results indicated that Actimmune had no effect on slowing the progression of IPF, and that none of the secondary endpoints achieved a statistically significant p-value. *Id.* at 684-85. As a result, "there was quite a strongly reinforced insight that . . . the trial had not provided evidence that Actimmune provides a clinically-meaningful effect." *Id.* at 685-86. After Dr. Fleming shared his

[3] Internal cross-references to a section of this brief's Statement of Facts are referenced as "Facts Section." Internal cross-references to a section of this brief's Legal Argument are referenced as "Argument Section."

views, which were shared by the other members of the DMC, *id.* at 687, Dr. Harkonen instructed others to disinvite Dr. Fleming from participating in a subsequent call with the FDA, as well as a later Steering Committee meeting. *Id.* at 2225-27, 2241.

On August 26, 2002, Dr. Steven Porter, InterMune's Senior Vice President of Clinical Research, discussed with Dr. Harkonen and other InterMune scientific personnel in Dr. Harkonen's presence the "fact that it was disappointing that the trial did not meet any of its endpoints" and that "[i]t was impossible to know whether these findings [the secondary endpoint of survival and the subgroup analysis] were real or not." *Id.* at 1364, 1366-69.

On August 27, 2002, Dr. Harkonen and a handful of other InterMune employees spoke unofficially by telephone with the medical review staff at the FDA about the results of the GIPF-001 clinical trial and the additional post-hoc subgroup analyses of the possible survival benefit. *Id.* at 1367, 1369-70. The FDA medical review staff advised them that the GIPF-001 clinical trial data were inconclusive, that the results were not adequate to get FDA approval for Actimmune to treat IPF, and that further clinical trials would be needed. *Id.* at 1370. As the minutes reflected, Dr. Walton stated that because "the physiologic measurements did not show any apparent treatment effect, the [survival benefit] in his opinion could be considered 'almost an anomalous finding in the face of no effect on pulmonary function and so warrants extra caution.'" *Id.* at 1955; Defense Trial Exhibit 671. Furthermore, the minutes reported, Dr. Walton said that "'[t]here is no way to give [the survival data] a meaningful p-value in the face of the failed primary endpoint.'" Defense Trial Exhibit 671.

After that meeting, Dr. Harkonen told Dr. Marianne Armstrong, InterMune's Senior Vice President of Global Regulatory Affairs and Corporate Compliance, who had drafted the minutes for the meeting with the FDA, that he was "very disappointed" that she had taken minutes of the meeting. Trial Transcript at 1856. Dr. Armstrong testified that it was standard procedure to take minutes of their calls with the FDA, and that she had previously shared meeting minutes from other calls with the FDA with no complaint from Dr. Harkonen. *Id.*

3. Dr. Harkonen Hiding the Draft Press Release from Others at InterMune

When drafting prior pharmaceutical-related press releases for InterMune, Weiss had had

access both to the raw data and to InterMune's medical staff. *Id.* at 1385, 2576-77. This time, although Weiss asked Dr. Harkonen for access to both, he got neither. *Id.* at 2576-78, 2580-81.

On August 25, Dr. Porter, who was in charge of pulmonary research at InterMune, complained to Dr. Harkonen about the short amount of time between the clinical people learning the trial results and the planned press release. *Id.* at 1358-59. Dr. Porter specifically told Dr. Harkonen in an email that it was a mistake to publish a press release without adequate time for the clinical scientists to think about it. *Id.* at 1359. "I can tell . . . that the data is not totally straightforward," Dr. Porter wrote, and asked for 24 hours. *Id.*

However, before August 27, 2002, no one other than Dr. Harkonen and Weiss had seen drafts of the press release. *Id.* at 2575-76. On August 27, 2002, during an off-site meeting, Dr. Armstrong, Dr. Porter, and Dr. Crager briefly viewed some parts of the release by looking over Weiss's shoulder while he edited the draft on a laptop computer. *Id.* at 2584-87. At that meeting, Dr. Crager talked briefly to Weiss about fixing an incorrect p-value, but after that, Dr. Harkonen told Dr. Crager not to bother Weiss because Weiss was busy. *Id.* at 2232-33. At that same meeting, when Dr. Armstrong asked Dr. Harkonen if he wanted her or InterMune's regulatory division involved with the writing of the press release, Dr. Harkonen told her not at that time, that he was working on a draft, and that he would share it with her later. *Id.* at 1842-43.

When Dr. Armstrong, Dr. Porter, and Dr. Crager gathered around Weiss to try to read the press release, Dr. Harkonen ordered Weiss out of the room and sent him back to InterMune's headquarters. *Id.* at 2587-88. David Cory, Senior Vice President of Sales and Marketing, testified that a visibly upset Dr. Harkonen castigated Weiss for sharing the draft press release with others. *Id.* at 2744-45.

Dr. Crager told people that he was available to help with the press release, and stayed at the office until 7:00 p.m. the night that the press release was issued. *Id.* at 2234, 2237. When he asked Weiss about helping draft the press release, Weiss told him he did not know whether he was allowed to share the draft with Dr. Crager, and that he would check with Dr. Harkonen. *Id.* at 2314-15. At trial, Weiss testified that he thought there was sufficient time that night for clinical employees to review the draft. *Id.* at 2655.

Some InterMune sales and marketing employees, including Keith Katkin, the Vice President of Pulmonary Marketing, provided input on the key messages they thought the press release should include. *Id.* at 1101-02, 2573; Government Trial Exhibit 51. Katkin received a copy of the release late on the 27th, so that he could prepare for the roll out of the press release to the field sales force the next morning. Trial Transcript at 1101-02.

Aside from Dr. Harkonen, no one with any clinical or statistical background, or who had reviewed the clinical trial data (including Dr. Crager, Dr. Porter, and Dr. Armstrong), was permitted by Dr. Harkonen to review the press release in its entirety before it was issued. *Id.* at 2577.

4. Dr. Harkonen and Dr. Raghu's Quote in the Press Release

Dr. Harkonen telephoned Dr. Raghu, informing Dr. Raghu that Dr. Harkonen had received the trial results, and "there was a mortality benefit." Trial Transcript at 871. Before the press release was issued, Dr. Raghu had not received "actual detailed data from the clinical trial," nor was he involved with drafting or approving the press release. *Id.* at 874. However, the press release attributed quotes to Dr. Raghu, including the following: "The mortality benefit is very compelling and represents a major breakthrough in [IPF]." Government Trial Exhibit 1. After the press release was issued, Dr. Fleming called Dr. Raghu to ask him about the press release and Dr. Raghu's quote that was in the press release. Dr. Raghu "had no idea what this press release was." Trial Transcript at 879.

5. Dr. Harkonen Misleading Rosenfield that Doctors at InterMune had Reviewed the Press Release

Although Rosenfield, InterMune's general counsel, reviewed drafts of the press release before it was issued, Dr. Harkonen did not tell him that the FDA had indicated skepticism about the results, or that InterMune's clinical division had asked for more time to review the data before the release went out, and had not reviewed the press release before it went out. *Id.* at 3123-24, 3266-69. Rosenfield was relying on the clinical and regulatory divisions to make sure that the scientific aspects of the press release were correct, and he testified that Dr. Harkonen misled him into believing that InterMune's clinical and regulatory staff had reviewed the press release; Rosenfield testified that he would not have signed off on the press release had he known otherwise. *Id.* at 3269,

3280, 3274-76.

6. Dissemination of the Press Release

PR Newswire's primary function is the distribution of press releases for its clients. Trial Transcript at 411. On August 28, 2002, at 1:58 a.m. Eastern Standard Time, the press release was submitted online to PR Newswire from Intermune. *Id.* at 427. At 8:02 a.m., Eastern Standard Time, PR Newswire distributed Dr. Harkonen's press release to approximately 4,000 newsrooms nationwide and 3,500 online databases and websites. *Id.* at 429-30. PR Newswire also put the press release on their website for journalists, and distributed it through free email lists for the biotech and pharmaceutical industries. *Id.* When the press release was issued, it was the only publicly available source of information regarding the results of the GIPF-001 clinical trial results. *Id.* at 688.

On September 5, 2002, Dr. Harkonen attended the Biocentury Newsmakers Conference in New York, where he addressed financial analysts, and told them that InterMune sales representatives had access to the press release and were using it. *Id.* at 2756-58. On August 28, 2002, the day the press release was issued, Megan Hann, an InterMune Regional Sales Director at that time, emailed a copy of the press release to the InterMune sales representatives working for her so they could in turn, "email [it] to doctors." Government Trial Exhibit 331. Sales representatives thought the press release was very effective with doctors, and used it with doctors to convince them to prescribe Actimmune for IPF patients. *Id.* at 2520, 2751-53; Government Trial Exhibits 64, 82, 89, 96, 331. At trial, a voice mail from an InterMune sales representative illustrated the effect the press release had on a physician. Government Trial Exhibit 96. In the voice message, the sales representative described a success story of a physician who "had been sitting on the fence in prescribing Actimmune," and filled out a prescription based on the press release. *Id.*

Priority Healthcare ("PHC") was a specialty pharmacy that was a business partner of InterMune. Trial Transcript at 1092. PHC was contracted to operate a call center for Intermune to provide patients and physicians with assistance with any inquiries regarding Actimmune. *Id.* at 1270. In September of 2002, InterMune instructed PHC to create a cover letter to attach to a copy of the press release so that both could be sent as a fax blast to doctors. *Id.* at 1279-80. InterMune approved the cover sheet prior to its being sent to doctors with the press release. *Id.* at 1285. In

mid-October 2002, PHC faxed this cover sheet and the press release to practicing pulmonologists throughout the United States. *Id.* at 1118, 1121; Government Trial Exhibits 6, 149.

Similarly, on September 6, 2002, Intermune instructed PHC to send a copy of the press release to all patients on Actimmune with their prescriptions, and to include a cover letter to patients discussing the GIPF-001 clinical trial results as reported in the press release. Government Trial Exhibit 120; Trial Transcript at 1281. From September 19, 2002 until October 16, 2002, PHC sent letter describing the GIPF-001 clinical trial results as reported in the press release to patients with their prescriptions of Actimmune. Trial Transcript 1289-90; Government Trial Exhibits 7, 134, 150.

7. Post-release: Dr. Harkonen Repeatedly Told Press Release was Fraudulent

After the press release came out, Dr. Harkonen was repeatedly told that the press release was fraudulent, yet he never retracted it or told InterMune's sales and marketing people to stop using it. Trial Transcript at 1125, 1214, 1694, 2488, 2805-06.

When Dr. Fleming first read the press release, he was "stunned," and found it to be "a serious misrepresentation of [the] truth as I understood it." *Id.* at 690. Dr. Fleming testified that in no way did the GIPF-001 clinical trial show that Actimmune reduced mortality in patients. Trial Transcript at 699. Additionally, while the press release noted a reduction in mortality for patients with mild to moderate disease, there is no mention that in the more severe patients, there was "an observed higher death rate on Actimmune compared to control." *Id.* at 702. Dr. Fleming regarded the misrepresentation in Dr. Harkonen's press release as the worst thing he had seen in 100 trials, stating such an extreme misrepresentation would be humorous if it was not so serious. *Id.* at 736.

On September 5, 2002, Dr. Fleming wrote and sent to InterMune a letter harshly criticizing the press release and explaining how the press release was false and misleading. *Id.* at 690; Government Trial Exhibit 3. In his letter, Dr. Fleming noted that the GIPF-001 clinical trial failed to achieve statistical significance on the primary endpoint. Trial Transcript at 692. Dr. Fleming also noted that even discounting the failure to hit the primary endpoint, and taking the p-values for the secondary endpoints as a basis for determining reliability, none of the secondary endpoints achieved statistical significance either. *Id.* at 697. He went on to describe his specific concerns with the press release, including, "[the] serious misrepresentation of results obtained from exploratory data

subgroup analyses." Government Trial Exhibit 3 at 4.

Moreover, as Dr. Fleming testified at trial, it was particularly problematic to suggest that a trend towards survival was real because the results of the GIPF-001 clinical trial indicated that Actimmune had no effect on lung function. Trial Transcript at 698-99. Dr. Fleming also noted that using the press release's FVC cut-off, for patients with severe IPF, there was a higher death rate among those on Actimmune than among those on the placebo, not what one would expect to see if Actimmune truly helped IPF patients live longer. *Id.* at 702-03.

After he received Dr. Fleming's letter, Dr. Harkonen flew to Seattle to meet with him to talk about the press release. *Id.* at 711-12. During a subsequent meeting, however, Dr. Harkonen falsely asserted to Dr. Fleming that the biostatistics and the clinical divisions had been involved in the August 28th press release. *Id.* at 711-12, 720-21.

Dr. Harkonen also met with Dr. Raghu at the European Respiratory Society ("ERS") meeting in Stockholm that September. *Id.* at 882. Dr. Raghu testified that Dr. Harkonen was very apologetic about the press release, and that Dr. Harkonen told him that he was drafting a second press release to set the record straight. *Id.* at 882.

In addition to Dr. Fleming and Dr. Raghu, Dr. Harkonen was told by Dr. Armstrong that Dr. Walton at the FDA was "truly dismayed" with the press release and thought that it "misled" the public, and that Dr. William Schwieterman, a former Division Director at the FDA and an InterMune consultant working on clinical trial design, was upset by the press release, calling it "the perfect example of how not to write a press release." *Id.* at 1860-73, Government Trial Exhibits 136, 140. Dr. Harkonen responded by telling Dr. Armstrong he did not want Schwieterman's opinion raised at an upcoming InterMune meeting. Trial Transcript at 1873.

Although InterMune issued a subsequent press release on September 18, 2002, Dr. Harkonen never retracted the original one; the sales force continued to use the August 28, 2002 press release to sell Actimmune as a treatment for IPF, not knowing that there was a problem with it. *Id.* at 1125, 1214, 1694, 2488, 2805-06; Government Trial Exhibit 5.

I. GIPF-007 Clinical Trial

Because the GIPF-001 clinical trial suggested that Actimmune might help IPF patients live

longer, InterMune conducted a subsequent clinical trial, the GIPF-007 clinical trial, also known as the INSPIRE clinical trial. *See* Fleming Decl. at ¶¶ 13-14. The GIPF-007 clinical trial was designed to test whether Actimmune helped IPF patients live longer, with survival as the primary endpoint of the trial. Declaration of Marcus Topel at ¶ 24 (hereafter "Topel Decl."), attached as Exhibit 1. This subsequent clinical trial was designed to test precisely what the August 28, 2002 press claimed was true, that Actimmune helped patients with mild-to-moderate IPF live longer. *Id.*

Significantly, "[t]he GIPF-007 clinical trial data reliably establish[ed a] lack of survival benefit by Actimmune in IPF patients with mild-to-moderate disease." Fleming Decl. ¶ 15. This "[l]ack of benefit was established in the very set of patients [] which Intermune's press release had made claims that Actimmune provided a very compelling mortality benefit that represented a major breakthrough in [IPF]." *Id.* at ¶ 16. The FDA issued an alert advising "of the early termination of the INSPIRE clinical study of Actimmune for idiopathic pulmonary fibrosis (IPF). The study was stopped because an interim analysis showed that patients with IPF who received Actimmune did not benefit. . . . An analysis showed that 14.5% of patients treated with Actimmune died as compared to 12.7% of patients treated with placebo." Topel Decl. at ¶ 24; FDA Alert, *Interferon Gamma 1-b (marketed as Actimmune)* (Mar. 9, 2007), attached as Exhibit 5.; Exhibit 6, Andrew Pollack, *Drug Maker Stops Work on Lung Disease Medicine*, N.Y. Times, Mar. 6, 2007, http://www.nytimes.com/2007/03/06/business/06drug.html?_r=0 ("Intermune, said yesterday that it was abandoning efforts to develop the product, Actimmune, as a treatment for idiopathic pulmonary fibrosis because results from a late-stage clinical trial [the GIPF-007 clinical trial] showed the drug did not prolong lives.").

"The interim GIPF-007 clinical trial results clearly showed that patients taking Actimmune as part of the GIPF-007 clinical trial died more frequently than those taking the placebo." Topel Decl. at ¶ 22. As a result of the GIPF-007 clinical trial, third party payers, *i.e.*, insurers, would no longer reimburse patients for prescriptions of Actimmune. *Id.* As Actimmune cost $50,000 per year per patient, the GIPF-007 clinical trial effectively ended the use of Actimmune to treat IPF. *Id.*

II. Indictment

On March 18, 2008, a federal grand jury indicted W. Scott Harkonen on two counts: (1) wire

fraud, in violation of 18 U.S.C. § 1343; and (2) misbranding, in violation of 21 U.S.C. §§ 331(k), 333(a)(2), 352(a). Doc. 1.[4]

The Indictment alleged that Dr. Harkonen, with intent to defraud, wrote the press release to falsely portray the GIPF-001 clinical trial results as establishing that Actimmune helped IPF patients live longer in order to induce doctors to prescribe and patients to take Actimmune to treat IPF. *Id.* at 6.

III. Dr. Harkonen's Legal Defense

A. Trial Preparation

In April 2008, one month after his indictment, Dr. Harkonen hired Marcus Topel of Kasowitz, Benson, Torres & Friedman ("the Kasowitz Firm") as his legal counsel to defend the wire fraud and misbranding charges against him. *See* Topel Decl. at ¶ 2. Initially, Topel, Lyn Agre, and William Goodman, of the Kasowitz Firm, were the core team preparing for Dr. Harkonen's trial and representing him at trial. *Id.* Additionally, numerous other attorneys at the Kasowitz Firm were involved in preparing Dr. Harkonen's defense. Topel, Agre, and Goodman are all partners at the Kasowitz Firm. *Id.* at ¶ 1; Declaration of Lyn Agre at ¶ 1 (hereafter "Agre Decl."), attached as Exhibit 2; Declaration of William Goodman at ¶ 1 (hereafter "Goodman Decl."), attached as Exhibit 3. Later in 2009, Ann Moorman, of the Law Offices of Ann Moorman, became a member of the core team involved in Dr. Harkonen's defense. Declaration of Judge Ann Moorman at ¶ 2 (hereafter "Moorman Decl."), attached as Exhibit 4. Moorman was an experienced litigator prior to beginning her term as a Superior Court Judge in January 2011. *Id.* at ¶ 1.

Dr. Harkonen also hired Ron Winchell, as his independent criminal counsel, to advise him on all legal matters associated with the case. Topel Decl. at ¶ 3. Winchell was an extremely experienced attorney focused on litigation. *Id.* Winchell was admitted to practice law in California in 1964 and was a graduate of Stanford Law School. *Id.* Topel, Agre, Goodman, and Moorman frequently updated Dr. Harkonen and Winchell on the status of the case, and Dr. Harkonen and

[4] Dr. Harkonen could be charged more than five years after the press release because he entered into tolling agreements with the government.

Winchell approved all major decisions the defense team made in representing Dr. Harkonen. *Id.*

Additionally, at the insistence and approval of Dr. Harkonen and Winchell, Sidley Austin LLP ("Sidley") attorneys were active participants in Dr. Harkonen's pre-trial and trial defense. *Id.* at ¶¶ 4-5. Paul E. Kalb, who is also a doctor and the head of Sidley's National Healthcare Practice, and Coleen Klasmeier, head of Sidley's Food, Drug and Medical Device Regulatory Practice, were involved in the Kasowitz Firm's attempts to identify and acquire expert witnesses who could possibly be used for Dr. Harkonen's defense. *Id.* at ¶ 4. Sidley attorneys compiled the initial expert list that was used to begin the search for experts for Dr. Harkonen's defense. *Id.* at ¶¶ 4, 10. Klasmeier and Kalb accompanied Agre when she traveled up and down the East Coast in search of experts. *Id.* at ¶ 4. Sidley attorneys also assisted with the pre-trial First Amendment motion filed in Dr. Harkonen's defense. *Id.* Klasmeier was a legal expert on the Federal Food, Drug, and Cosmetic Act ("FDCA") and was involved to a limited extent in the defense of the felony misbranding charge against Dr. Harkonen. *Id.* Sidley's total billing through verdict was $633,009.09. *Id.*

1. Identifying Expert Issue in the Case

Early on, based on the allegations in the indictment, Topel, Agre, and Goodman determined the key expert issue was whether the press release was false or misleading in so far that it represented that the GIPF-001 clinical trial results showed that Actimmune had a statistically significant survival benefit for IPF patients. *Id.* at ¶ 8. Topel, Agre, and Goodman, along with Klasmeier and Kalb, identified biostatisticians as the relevant type of expert to opine whether the press release was false or misleading. *Id.*

The defense team was aware that Dr. Thomas Fleming likely would be the government's expert biostatistician who would testify at trial. *Id.* at ¶ 9; Moorman Decl. at ¶ 7. Dr. Fleming was the preeminent biostatistician in the United States. *See* Trial Transcript at 644-53. Dr. Fleming's opinion regarding the press release was clear. *See* Government Trial Exhibit 3. On September 5, 2002, seven days after the press release was issued, Dr. Fleming wrote his critical letter to InterMune, in his capacity as Chair of the DMC for the GIPF-001 clinical trial, explaining why he believed that the press release was false and misleading. *Id.* at 4-6.

Aware of the prestige of the government's expert witness, and his criticism of the press

release, Dr. Harkonen's defense team began to seek out defense expert biostatisticians. *See* Topel Decl. at ¶ 9.

2. Search for Biostatisticians

Under Topel's direction, Agre, Goodman, Klasmeier, and Kalb, among others, were tasked with identifying, researching, interviewing, and acquiring potential expert witnesses to testify on Dr. Harkonen's behalf at trial. *See* Topel Decl. at ¶¶ 10, 12. Dr. Harkonen's defense team began their expert search by trying to secure biostatisticians for Dr. Harkonen's defense. *See id.* at ¶¶ 8-10. Sidley provided an initial list of potential expert witnesses for Dr. Harkonen's defense. *See id.* at ¶¶ 4, 10.

The defense team conducted an extensive nationwide search for defense biostatisticians. *Id.* at ¶ 12. Most of the biostatisticians that the defense contacted stated that the press release was false or misleading and that the GIPF-001 clinical trial results did not "demonstrate" a survival benefit. *See, e.g., id.* at ¶¶ 13.b., 13.c. Some of these biostatisticians were hostile to Dr. Harkonen's defense. *Id.* at ¶ 11. Several of the biostatisticians that the defense contacted did not want to testify in opposition to Dr. Fleming, who was well known and widely regarded as a leader in the field of interpreting clinical trial results. *See, e.g., id.* at ¶¶ 12, 13.b.

From May 2008 until Dr. Harkonen's trial began, Agre spent almost every day searching for biostatisticians for Dr. Harkonen's defense. *Id.* Agre was frequently conferring with Topel, Goodman, Klasmeier, and Kalb who were also actively searching for biostatisticians during that time period. *Id.* Agre flew all over the country interviewing potential biostatisticians for Dr. Harkonen's defense. *Id.* at ¶¶ 4, 10, 13. Klasmeier and Kalb accompanied Agre to some of the biostatistician interviews on the East Coast. *Id.* at ¶ 4.

After Topel, Agre, Goodman, Klasmeier, Kalb, and other associates at the Kasowitz Firm spent over a year scouring the country for biostatisticians willing to state the press release was accurate, the only two biostatisticians in the entire country whom they found that were willing to say Dr. Harkonen's press release was not false or misleading were Dr. Lawrence Mayer and Dr. Patrick Hannon. Topel Decl. at ¶ 14.

Dr. Mayer earned his Ph.D. in 1971, and at the time he was retained by Dr. Harkonen's

defense, he was a Professor of Public Health and Psychiatry at John Hopkins University Bloomberg School of Public Health and School of Medicine, a Professor of Biostatistics at Arizona State University and a Professor of Epidemiology at the University of Arizona, along with holding several other academic and medical appointments. *Id.* at ¶ 15. He had authored over 70 published articles and taught classes in biostatistics and related subjects. *Id.*

Agre, Topel, and other members of Dr. Harkonen's defense team met in person or talked by telephone over twenty times with Dr. Mayer, beginning in February 2009. *Id.* at ¶ 16. On March 3, 2009 and March 31, 2009, Agre traveled to Phoenix to meet with Dr. Mayer. *Id.* Dr. Mayer also came to San Francisco to meet with Dr. Harkonen's defense team three times, in April 2009, June 2009, and in September 2009, in anticipation of testifying at trial. *Id.*

At all times prior to trial, Dr. Mayer consistently stated what was put in his expert disclosure: "Dr. Mayer will opine on the accuracy of the statements made in InterMune's August 28, 2002 press release and the fact that none of them is false or misleading. The press release was a true and accurate description of the findings of InterMune's GIPF-001 clinical trial." *Id.* On May 21, 2009, May 22, 2009, and May 26, 2009, Agre reviewed Dr. Mayer's expert disclosure proffer with him line by line, confirming his opinion that the press release was accurate. *Id.* Moorman also confirmed the expert disclosure line by line with Dr. Mayer. *Id.* Billing records from the Kasowitz Firm show that Dr. Mayer charged $159,186 for the primary purpose of testifying to the accuracy of the press release at Dr. Harkonen's trial. *Id.*

Dr. Hannon was the other biostatistician who was willing to state that the press release was accurate. *Id.* at 18. Dr. Hannon earned a Ph.D. in Statistics from Old Dominion University in Norfolk, Virginia, in 1998. *Id.* Dr. Hannon had only ten years of experience as a biostatistician at the time of trial, and had far less clinical trial experience than the government's expert, Dr. Fleming. *Id.* Dr. Hannon's Curriculum Vitae indicated only one published article and showed no academic appointments. *Id.* As one of only two biostatisticians that Topel, Agre, Goodman, Klasmeier, and Kalb could find in the nation who were willing to state the press release was accurate, Dr. Hannon was retained for Dr. Harkonen's defense. *Id.*

On January 30, 2009, Agre traveled to Raleigh/Durham, North Carolina for an initial in-

person meeting with Dr. Hannon to discuss the GIPF-001 clinical trial results and the press release interpreting those results. *Id.* Agre later met with Dr. Hannon in New York City on March 12, 2009, to further discuss his potential testimony. Topel attended a significant portion of this meeting by telephone. *Id.*

3. Search for Pulmonologists

In addition to trying to secure biostatisticians for Dr. Harkonen's defense, Topel, Agre, Goodman, Klasmeier, and Kalb decided to seek out pulmonologists to possibly testify in Dr. Harkonen's defense at trial. Topel Decl. at ¶ 19. As they prepared for trial, the defense team identified four primary areas on which an expert pulmonologist could potentially testify: (1) explaining the IPF disease; (2) stating Actimmune helped IPF patients; (3) stating that pulmonologists could read and understand the GIPF-001 clinical trial results in the press release and that pulmonologists would not be misled by the press release; and (4) stating doctors do not rely solely on press releases when making prescribing decisions. *Id.* at ¶ 36.a.

As with the biostatisticians, the search for pulmonologists proved difficult. *See id.* at ¶¶ 20-23. Again, Topel, Agre, Goodman, Klasmeier, and Kalb had to conduct a nationwide search for defense pulmonologists. *Id.* at ¶ 20. Among the many pulmonologists Dr. Harkonen's attorneys contacted were those on the Steering Committee for the GIPF-001 clinical trial who had not previously made negative statements about Dr. Harkonen or the press release to the government. *Id.* at ¶ 21. Dr. Ganesh Raghu, Chair of the Steering Committee and also a principal investigator for the GIPF-001 clinical trial, had already talked to the government, and would later serve as a government witness at Dr. Harkonen's trial. *Id.*

On multiple occasions, Topel, Agre, and others tried to contact Steering Committee pulmonologists Dr. Kevin Brown, Dr. Talmadge King, and Dr. Paul Noble. *Id.* Of them, all but Dr. Brown either refused or did not return the calls from Dr. Harkonen's defense team. *Id.* Dr. Brown left a hostile voice message for Agre stating his disdain and distrust of Dr. Harkonen and the statements in the press release. *Id.* Dr. Brown stated that no one on the Committee would support Dr. Harkonen's position. *Id.* He also asked Agre not to contact him again. *Id.* None of the pulmonologists on the GIPF-001 clinical trial Steering Committee would help Dr. Harkonen's

defense, and one of them, Dr. Raghu, would testify against Dr. Harkonen. *Id.*

Dr. Harkonen's attorneys contacted numerous pulmonologists throughout the country to try to secure potential defense pulmonologists, with little success. *Id.* at ¶¶ 20-23. Among the efforts to acquire pulmonologists for Dr. Harkonen's defense, Agre and a paralegal from the Kasowitz Firm contacted more than 200 doctors on the Actimmune Prescribers list, which is a list of pulmonologists and other doctors who prescribed Actimmune from October 2000-September 2001. *Id.* at ¶ 23. They received only two responses from more than 200 phone calls. *Id.*

The nationwide search for pulmonologists willing to testify for Dr. Harkonen's defense resulted in two defense pulmonologists, Dr. Joseph Zibrak and Dr. Roger Maxfield. *Id.* at ¶ 25. Topel, Agre, Goodman, and Moorman were "confident in the credentials of Dr. Zibrak and Dr. Maxfield as pulmonology experts." *Id.*

The expert disclosures for Dr. Zibrak and Dr. Maxfield stated that each of these pulmonologists would "describe IPF, IPF's symptoms, and treatment options for IPF patients," explain that Actimmune was a "valid treatment option" for IPF patients, and "opine that physicians do not make treatment decisions solely on the basis of a press release." Doc. 117 at 4, 8.

4. Risks of Pulmonologist Testimony

As Dr. Harkonen's case moved closer to trial, Topel, Agre, Goodman, and Moorman became aware of the risks associated with defense pulmonologist testimony. As previously discussed, the GIPF-007 clinical trial – which was designed to test exactly what Dr. Harkonen's press release claimed was true, that Actimmune helped patients with mild-to-moderate IPF live longer – was terminated early because the results "showed the drug did not prolong lives." Exhibit 6; *see supra* Facts Section I.I.

On June 10, 2009, Dr. Harkonen's defense team filed a motion *in limine* to exclude the admission of the GIPF-007 clinical trial results at Dr. Harkonen's trial. Doc. 127. Dr. Harkonen's defense team argued that the GIPF-007 clinical trial results were irrelevant, because the results were not known until more than three years after Dr. Harkonen had left InterMune, and would be unduly prejudicial against Dr. Harkonen. *Id.* The government argued for the admission of the GIPF-007 clinical trial results, and on June 17, 2009, filed its opposition to Dr. Harkonen's motion *in limine*.

Doc. 144. The government argued the GIPF-007 clinical trial results were "directly relevant to an element of the [felony misbranding charge]" and needed to be available to cross-examine the defense team's proposed experts. *Id.* at 3-4. The two sides argued their positions at a Pretrial Conference on June 24, 2009. Citing "confusion to the jury" as her concern, Judge Patel stated: "I don't want to hear any reference to the results of the [GIPF-007 clinical trial] . . . ." June 24, 2009, Pretrial Conference Transcript at 23. While noting that circumstances at trial could cause the GIPF-007 clinical trial results to be admissible, she did not "want to hear anything about test results from that without a side bar." *Id.* 24-25.

On July 16, 2009, the government filed a renewed opposition to Dr. Harkonen's motion *in limine* to exclude the GIPF-007 clinical trial results, citing a peer-reviewed article "authored by 11 doctors and a biostatistician [which] was published and clearly explains the results of the [GIPF-007 clinical] trial [that] conclusively establish[ed] the false and misleading nature of the statements in the Defendant's August 28, 2002 press release and other Actimmune labeling." Doc. 161 at 2. On July 20, 2009, Dr. Harkonen's defense team filed a reply to the government's renewed opposition, again asserting that the GIPF-007 "are irrelevant to the charged crimes and are unduly prejudicial." Doc. 163 at 2. On August 6, 2009, at a Pretrial Conference, Judge Patel ruled the government was not going to be able to prove the falsity of the press release through the admission of the GIPF-007 clinical trial results, because she felt "that would be misleading to the jury." August 6, 2009, Pretrial Hearing Conference Transcript at 60.

While the Court had preliminarily excluded the admission of the results of the GIPF-007 clinical trial, if the defense did anything to "open the door," the Court could allow the admission of the GIPF-007 clinical trial results. Topel Decl. at ¶ 36.a.ii. Therefore, if a pulmonologist, such as Dr. Zibrak or Dr. Maxfield, were called to testify as part of Dr. Harkonen's defense, on cross-examination, there was the risk that the GIPF-007 clinical trial results could be admitted. *Id.* Dr. Harkonen's defense team felt admission of the GIPF-007 clinical trial results would be a disaster because it would show the press release was false and misleading, and it would make Actimmune look like "high-priced 'snake oil.'" *Id.* at ¶ 24. For instance, if a defense pulmonologist stated that Actimmune was effective for treating IPF, on cross-examination, he would likely have to admit that

he no longer prescribed Actimmune to treat IPF. Declaration of Dr. Joseph Zibrak doc. 284, ¶ 7 (hereafter "Zibrak Decl.") ("I do not currently prescribe interferon gamma-1b for IPF.").

5. Search for Other Experts

Due to the extreme difficulty Dr. Harkonen's defense team was having finding biostatisticians and pulmonologists willing to support Dr. Harkonen's defense, his attorneys also contacted other doctors and other potentially relevant experts for possible use in Dr. Harkonen's defense. Topel Decl. at ¶ 26. The only other credible and potentially relevant doctors the defense team was able to find who were willing to testify for Dr. Harkonen's defense were Dr. Kathryn Zunich and Dr. David Katz. *Id.* at ¶ 27.

Dr. Zunich had more than twenty-three years of experience working with clinical trials, and she served as a medical and regulatory affairs consultant to the pharmaceutical industry. *Id.* at ¶ 27.a. Dr. Zunich's expertise was in the conduct of clinical trials. *Id.* She was available if needed to testify that the GIPF-001 clinical trial was a well-run clinical trial. *Id.*

Dr. Katz stated that the press release was accurate. *Id.* at ¶ 27.b. Dr. Katz was an experienced medical doctor who was likeable and could discuss medical issues in simple terms. *Id.* Because of these skills, he had appeared on the Oprah Winfrey Show several times to discuss medical issues in easy to understand terms. *Id.* However, he was not a biostatistician or a pulmonologist; nor did he treat patients with IPF. *Id.* If needed, Dr. Katz was available to explain the testimony of a defense biostatistician in layman's terms. *Id.*

6. Doctor Tapes Cited in the Petition

The defense team had tapes of pulmonologists speaking about the GIPF-001 clinical trial results at the ERS and College of Chest Physicians ("CHEST") medical conferences, and a presentation by Dr. Steven D. Nathan. Topel Decl. at ¶ 46. The defense team strategically chose not to use these tapes after they were reviewed by Topel, Agre, Goodman, and other attorneys at the Kasowitz Firm at least two times before Dr. Harkonen's trial. Topel Decl. at ¶¶ 46-49.

At the ERS conference, in Stockholm in September 2002, while not explicitly criticizing the press release, but while responding to a question referencing the press release, Dr. Noble noted that using the 55% FVC as a cutoff would be subject to criticism as a subset analysis. *See* DVD:

Presentations at ERS conference in Stockhom, Sweden (Sept. 15, 2002) INR-MEDIA-0034 at 33:40-34:43 (hereafter "INR-MEDIA-0034"), attached as Exhibit 10.

At the CHEST conference in San Diego on November 5, 2002, regarding the GIPF-001 clinical trial data, Dr. Raghu stated: "I sit with the patient and talk it over in terms of the disease that is concerned, and give him or her the options, and have the patient come into the partnership in terms of the decision-making and proceed in terms of treatment. . . . And then leave it up to the patient to decide what they think is the best to do given the data that we presently have." DVD: Presentations at CHEST conference in San Diego, California (Nov. 5, 2002) WOOD-MEDIA-0010 at 1:10-2:00 (hereafter "WOOD-MEDIA-0010"), attached as Exhibit 11.

At the CHEST conference in San Diego on November 5, 2002, Dr. Gregory Tino stated: "I'm disappointed that I don't think the study definitively answered the question of interferon gamma's efficacy of the disease . . . . I sit down with the patients, and I show them the data, and I plan on showing them the data. . . . My hypothesis was that if the drug is going to work it's going to work in patients with mild or to moderate disease." *Id.* at 3:15-4:15.

At the CHEST conference in San Diego on November 5, 2002, Dr. Marvin Schwarz noted that while there "appears to be a survival benefit . . . as everybody has alluded to we need more time. . . . My feeling is, I certainly discuss [the GIPF-001 clinical trial data] with every patient that I see." *Id.* at 4:15-5:40.

In 2002, Dr. Nathan gave a presentation, which was recorded. DVD: Audio Presentation by Dr. Steven D. Nathan INR-MEDIA-0057 (hereafter "INR-MEDIA-0057"), attached as Exhibit 12. On the tape, Dr. Nathan stated: "The study failed to meet its primary endpoint and in that regard is a negative study." *Id.* at 13:57-14:02. Dr. Nathan also stated: "I think the results of the study have been controversial to say the least." *Id.* at 17:33-17:37. Twice during Dr. Nathan's presentation, doctors listening to his presentation called in and shared a similar criticism, that there was no evidence that Actimmune resulted in improved lung function. *Id.* at 43:06-45:15; 55:45-1:01:30. On the tape, Dr. Nathan could not answer this critique of the study. *Id.* at 43:15-43:32. Dr. Nathan agreed that he would have expected the improved lung function to occur before the improvement in survival. *Id.* at 44:28-44:38.

After the review of these tapes at least twice by Topel, Agre, Goodman, and other attorneys at the Kasowitz Firm, Topel, Agre, Goodman, and Moorman discussed whether these tapes could be useful to Dr. Harkonen's defense. Topel Decl. at ¶¶ 46-49. Topel, Agre, Goodman, and Moorman rejected using the tapes at Dr. Harkonen's trial, because, overall, each doctor's presentation on the tapes was either irrelevant or harmful to Dr. Harkonen's defense. *Id.* at ¶ 48. Despite the opinion of the defense team that the tapes were not useful to the defense, Agre and other attorneys working on Dr. Harkonen's defense tried to contact some of the doctors on those tapes to see if they could be helpful to the defense. *Id.* at ¶ 49. Agre tried to call Dr. Noble and Dr. Marvin Schwarz at least twice asking them to help with Dr. Harkonen's defense. *Id.* These doctors did not return her calls. *Id.*

B. Trial

1. Government's Opening Statement

In its opening, the government stated that the GIPF-001 clinical trial failed completely to show that Actimmune was in any way an effective treatment for IPF. Trial Transcript at 276. The government stated that Dr. Crager and others spoke to Dr. Harkonen about the data on mortality and made it clear that these "after-the-fact analyses" (analyses that were not focused on what the trial was designed to test) could not be relied on to actually prove anything, and that another trial would be needed. *Id.* at 279.

The government did not dispute that the GIPF-001 clinical trial was properly conducted, nor did it argue that post-hoc subgroup analyses were improper. On the contrary, the government stated that "it's fine to look at data to design the next trial. It's fine to share all of your information with other scientists and have a good, robust scientific discussion." *Id.* at 279-80. And rather than analyzing the data to design the next trial, because GIPF-001 was a failure, Dr. Harkonen ran a number of different analyses and picked the best number that made it look like patients lived longer, and he left out the other numbers that didn't look as good, making it sound like the trial proved something it didn't actually prove. *Id.* at 280. The press release he put out stated that the "Phase III data demonstrating a survival benefit of Actimmune in IPF reduces mortality by 70 percent in patients with mild to moderate disease." *Id.* The government contended that the press release

misrepresented the significance, and in particular, the statistical significance of the inconclusive results by falsely representing that they showed a statistically significant survival benefit.

2. Dr. Harkonen's Representation at Trial

Each day at trial, Dr. Harkonen had Topel, Agre, and Moorman, three experienced trial lawyers, by his side. Topel Decl. at ¶ 31. At times, Goodman was also present at trial. *Id.* Numerous attorneys at the Kasowitz Firm were working behind the scenes on Dr. Harkonen's defense throughout trial. *Id.* Additionally, Winchell attended trial every day to provide experienced and independent legal advice to Dr. Harkonen. *Id.*

On August 18, 2009, Topel delivered the opening statement for Dr. Harkonen's defense at trial. *Id.* at ¶ 30. In his opening, Topel laid out numerous ways to challenge the government's case against Dr. Harkonen, including that Dr. Harkonen had no intent to defraud because he believed the press release was true. *Id.*; Trial Transcript at 293, 302, 326-27. Topel also briefly mentioned that Dr. Mayer, Dr. Zibrak, and Dr. Katz would testify in Dr. Harkonen's defense. Topel Decl. at ¶ 30; Trial Transcript at 324-25. Topel delivered his opening statement before the government's case-in-chief, which lasted approximately five weeks. Topel Decl. ¶ 30.

3. Beneficial Defense Evidence Elicited at Trial

At trial, Topel and Moorman elicited testimony on cross-examination and on direct that Topel, Agre, Moorman, and Goodman felt was beneficial to Dr. Harkonen's defense. *See id.* at ¶¶ 33, 37. In this testimony, many government witnesses admitted to making statements similar to those in Dr. Harkonen's press release. *See id.* at ¶ 33.

i. Dr. Crager

Dr. Crager was cross-examined by Topel. *Id.* at ¶ 33.g. On August 27, 2002, Dr. Crager signed and filed a patent application for Actimmune making numerous assertions. Defense Trial Exhibits 115, 116. Dr. Crager directed the patent attorneys to edit the application to include: "There's strong statistical evidence that interferon gamma has a positive survival effect in these patients." Trial Transcript at 2381; Defense Trial Exhibit 116 at 18. The final version of the patent application included: "There is strong statistical evidence that interferon gamma-1B has a positive effect in these patients." Trial Transcript at 2382, Defense Trial Exhibit 116 at 18. Again in relation

to the patent, Dr. Crager agreed with the statement: "[D]espite missing the primary endpoint, there was still statistically significant improvement in probability of survival, which is another way of saying survival benefit or mortality benefit[.]" Trial Transcript at 2390-91; Defense Trial Exhibit 116 at 18. On August 27, 2002, one day before the press release was issued, InterMune filed the patent application at Dr. Crager's direction, with his signature, listing Dr. Crager as the inventor of Actimmune, and including statements drafted by Dr. Crager that were nearly identical to the statements in Dr. Harkonen's press release. *See* Trial Transcript at 2381-83, 88-91.

When speaking with Dr. Fleming on August 29, 2002, Dr. Crager mentioned there was a press release, but voiced no negative opinion regarding that press release. *Id.* at 2395. Dr. Crager submitted at a September 4, 2002 Joint Steering Committee and DMC[5] Meeting, a clinical report that he had received from Pharmanet, the CRO for the GIPF-001 clinical trial, on August 23, 2002, that contained the subgroup analyses that he had run on his own and at Dr. Harkonen's direction. Defense Trial Exhibit 524. This report had the p-value of 0.004 for FVC $\geq$ 55%. *Id.* As in Dr. Harkonen's press release, there was no qualification of the p-value to inform the reader that this result was from a retrospective subgroup analysis. Trial Transcript at 2344-46.

On August 23, 2002, before the press release was issued, Dr. Crager prepared a Key Results slide that he presented to Dr. Harkonen and Dr. Pennington. Government Trial Exhibit 12. One of the key results was a "Stronger, significant effect (p=0.004) among patients with BL FVC $\geq$ 55%." *Id.* Dr. Crager did not qualify this or any result in the slide as a retrospective subgroup analysis. *See id.*

ii. Dr. Armstrong

On cross-examination, Dr. Armstrong testified that Dr. Crager, Dr. Porter, Dr. Bradford, and Dr. Pennington all emphasized the mortality data of the GIPF-001 clinical trial on a call with the FDA on August 27, 2002. Trial Transcript at 1955. Dr. Armstrong testified that at a Steering

[5] Defense Trial Exhibit 524 notes the report was provided at a Joint Steering Committee and DSMB Mtg. DSMB stands for Data Safety Monitoring Board. The terms DSMB and the DMC are two different names for the same group that monitors patient safety in a clinical trial. Trial Transcript at 364-65.

Committee meeting, also on August 27, 2002, InterMune's clinical researchers highlighted the mortality benefit resulting from the GIPF-001 clinical trial, again citing the p-value of 0.004. *Id.* at 1980.

Dr. Armstrong never memorialized her concerns with the press release. *Id.* at 1997. On September 19, 2002, when she expressed her discomfort with the press release to Dr. Harkonen for the first time, Dr. Harkonen suggested she call Dr. Walton to see what he thought about the press release. *Id.* at 2045-46. Dr. Armstrong made no recommendation for any action to be taken regarding the press release after speaking with Dr. Walton. *Id.* at 2049. Dr. Armstrong testified that in the fall of 2002, when discussing his frustrations with InterMune's sales and marketing, Dr. Harkonen told her, "he [Harkonen] would get Mr. Cory in line, even if it meant sales were 125 million rather than 400 million." *Id.* at 2063. When interviewed in November 2002 by Dewey & LeBoeuf attorney Matthew Walsh regarding issues surrounding the press release, Dr. Armstrong expressed no dissatisfaction with the press release. *Id.* at 2008-12.

On May 7, 2003, in anticipation of a meeting with the FDA, Dr. Armstrong called Dr. Walton to describe InterMune's strategy to get FDA approval for Actimmune to treat IPF. *Id.* at 2021; Defense Trial Exhibit 689. As part of that strategy, Dr. Armstrong stated InterMune was relying on data from the GIPF-001 clinical trial in seeking FDA approval. Trial Transcript at 2021. Dr. Armstrong stated that part of InterMune's submission to FDA for approval would be the "three clinical trials that demonstrate a survival benefit," one of which was the GIPF-001 clinical trial. Defense Trial Exhibit 689.

Also on cross-examination, Dr. Armstrong testified that on June 9, 2006, when Dr. Armstrong was Senior Vice President of Regulatory Affairs at InterMune, she worked with Dr. Porter on the final clinical study report for the GIPF-001 clinical trial, which was submitted to the FDA. Trial Transcript at 2026-2030; Government Trial Exhibit 288. Dr. Armstrong testified that the report contained statements that were based on post-hoc analyses of the GIPF-001 data, including that Actimmune had a "demonstrated survival benefit." Trial Transcript at 2029; Government Trial Exhibit 288 at 95.

iii. Dr. Porter

On cross-examination, Dr. Porter testified that in 2006, the final clinical study report on the GIPF-001 clinical trial was filed with the FDA. Trial Transcript at 1512-15; Government Trial Exhibit 288. Dr. Porter was the author of the clinical study report; he signed the clinical study report, and he filed it with the FDA. Government Trial Exhibit 288. Dr. Porter testified that the report stated Actimmune had a "demonstrated survival benefit" for IPF patients. Trial Transcript at 1512-15; Government Trial Exhibit 288 at 95. The report further stated that this survival benefit was based on post-hoc analysis. *Id.*

Also on cross-examination, Dr. Porter testified that he, along with Dr. Harkonen, Dr. Bradford, Dr. Starko, and Dr. Pennington, authored a September 27, 2002 letter sent to Dr. Fleming, defending the analysis of the GIPF-001 clinical trial results as reported in the press release. Defense Trial Exhibit 114. Dr. Bill Bradford and Dr. Karen Starko were Senior Directors of Clinical Research at InterMune. *Id.* at 5.

iv. Other Government Witnesses

On cross-examination, Dr. Wayne Hockmeyer testified that he believed the dispute between Dr. Harkonen and Dr. Fleming over the press release might have been just "an academic disagreement between two keen, opinionated medical minds." Trial Transcript at 1598. Dr. Hockmeyer also stated Dr. Pennington seemed aligned with Dr. Harkonen and the rest of the team on evaluating the results of the trial; that there was a consensus that the GIPF-001 clinical trial results showed a survival benefit. *Id.* at 1617-18.

On direct, Rosenfield testified he was comfortable with the use of "demonstrated" and "demonstrating" in the press release because "it was consistent with [Dr.] Mike Crager and [Dr.] Jim Pennington's view, and the fact we filed a patent, and we thought we had something that was really statistically significant…" *Id.* at 3137-38.

On cross-examination, Dr. Raghu testified that in October 2002, two months after the press release was issued, he wrote a letter to the Director for Research and Industry Relations Support at the University of Washington, discussing his involvement with the GIPF-001 clinical trial. In that letter, Dr. Raghu stated: "the [GIPF]-001 study has been so successful. . . ." Defense Trial Exhibit

512. Additionally, Dr. Raghu was quoted in the press release favorably describing the mortality benefit shown by the results of the GIPF-001 clinical trial: "The mortality benefit is very compelling and represents a major breakthrough in this difficult disease . . . . Interferon gamma-1b is the first treatment ever to show any meaningful clinical impact in this disease in rigorous clinical trials, and these results would indicate that Actimmune should be used early in the course of this disease in order to realize the most favorable long-term survival benefit." Government Trial Exhibit 1.

On cross-examination, Weiss testified that before including Dr. Raghu's quote in the press release, he read that quote to Dr. Raghu, and Dr. Raghu agreed to have his quote used in the press release. Trial Transcript at 2589-90. Weiss also testified that Dr. Pennington agreed to have his quote used in the press release. *Id.* at 2591-92. Dr. Pennington was the Chief Medical Officer at InterMune in charge of conducting the GIPF-001 clinical trial. *Id.* at 1588-89, 1601. In the press release, Dr. Pennington stated: "We felt we had an ethical obligation to get this important news out about the survival benefit of Actimmune so physicians can evaluate it when making treatment decisions for their patients . . . . We now have two well-controlled trials in IPF patients supporting a survival benefit, providing what we believe is compelling rationale for consideration of Actimmune for the treatment of patients with this disease." Government Trial Exhibit 1.

On cross-examination, Walton testified that while the FDA typically wants two positive clinical trials before approving a drug to treat a disease, the FDA might consider the GIPF-001 clinical trial, which missed its primary endpoint, as one of those two trials for FDA approval of Actimmune to treat IPF. Trial Transcript at 575-77.

On cross-examination, Dr. Fleming testified that he never asked for the press release to be retracted. *Id.* at 737-40.

4. Decision to Rest the Case Without Calling the Experts

i. Wednesday, September 16, 2009: Trial Team Evaluates Case

On Wednesday, September 16, 2009, Topel, Agre, Moorman, and Goodman met to evaluate the case. Topel Decl. at ¶ 35. Based on the testimony elicited at trial, Dr. Harkonen's defense team felt confident they were ahead of the government. *See id.* After they listed the beneficial testimony already elicited at trial, Moorman noted that this evidence was ample to support the defense

argument that the press release was accurate, and raised more than reasonable doubt as to Dr. Harkonen's intent to defraud because there was substantial evidence that Dr. Harkonen could have reasonably believed the press release to be accurate. *Id.*; Moorman Decl. at ¶ 27. Topel and Agre concurred that the cross-examination testimony from Dr. Crager, Dr. Armstrong, Dr. Porter, Dr. Hockmeyer, Rosenfield, Dr. Raghu, Weiss, Dr. Walton, and Dr. Fleming at trial had obviated the need for defense experts. Topel Decl. at ¶¶ 33, 35; *see supra* Facts Section III.B.3.

Later that evening, Topel, Agre, and Moorman conferred with Goodman, who also concurred in the decision that there was no need to call any defense expert. Goodman Decl. at ¶ 35.a. In particular, Topel, Agre, Moorman, and Goodman all agreed the best strategic decision for Dr. Harkonen's defense was not to call a defense pulmonologist, because at this point having a non-biostatistician testify about the press release was of little value to Dr. Harkonen's defense, while at the same time posed definite risks that the GIPF-007 clinical trial results (the INSPIRE trial) could become admissible during the cross-examination of a defense expert. Topel Decl. at ¶ 36.a.; *see supra* Facts Section III.A.4. The defense team still thought that Dr. Mayer could help Dr. Harkonen's defense, but did not think they needed him to testify to raise reasonable doubt and to prevail at trial. Topel Decl. at ¶¶ 35, 36.f.

ii. Thursday, September 17, 2009: At Final Prep Session, Dr. Mayer Completely Changes His Opinion and States Dr. Harkonen's Press Release Was Misleading

After trial on Thursday, September 17, 2009, Topel, Agre, Moorman, and Goodman met with Dr. Mayer in a final prep session for his testimony. ¶ 38. Since he had been retained in April 2009, Dr. Mayer was the singular witness with whom the defense team spent the most time reviewing, verifying, and preparing his testimony. *Id.* at ¶ 39. In the course of his relationship with Dr. Harkonen's defense, Dr. Mayer charged $159,186, specifically to prepare him as an expert witness for Dr. Harkonen's trial. *Id.*

In all discussions prior to the September 17th meeting with Dr. Harkonen's attorneys, Dr. Mayer stated the press release was accurate. *Id.* In fact, Dr. Harkonen's defense submitted two expert disclosures stating Dr. Mayer considered the press release accurate, which were confirmed, line by line, multiple times with Dr. Mayer, by Topel, Agre, and Moorman, before filing them with

the Court. *Id.* at ¶¶ 16, 39. Topel had personally prepped Dr. Mayer for testifying several times in the week leading up to his expected testimony. *Id.* at ¶ 39. "During those earlier prep sessions, Dr. Mayer maintained his opinion that the press release was accurate." *Id.* However, at the September 17, 2009 meeting, on the eve of his testimony, Dr. Mayer stated the press release might be somewhat misleading. *Id.* This change was completely unforeseen by Dr. Harkonen's defense team. *Id.*

As Dr. Mayer had flipped on the key expert issue in the case, Dr. Harkonen's trial team, Topel, Agre, Moorman, and Goodman, all agreed Dr. Mayer could not be called as a defense witness. *Id.* at ¶ 40. Before this change, the defense team thought Dr. Mayer could benefit Dr. Harkonen's defense. *Id.* at ¶ 36.f. After Dr. Mayer changed his opinion, Dr. Harkonen's defense team felt it was obvious that Dr. Mayer could no longer be a witness for the defense. *Id.* at ¶ 40. Dr. Harkonen's defense team fully intended to call Dr. Mayer until this last-minute change to his testimony. *Id.* at ¶¶ 38, 40.

With Dr. Mayer no longer a viable option as an expert for Dr. Harkonen's defense, the defense team then considered whether it would help Dr. Harkonen's defense to call Dr. Hannon, the only other biostatistician they had found who was apparently willing to testify that the press release was accurate. *Id.* at ¶¶ 18, 41. Topel, Agre, Moorman, and Goodman had already agreed that no defense expert testimony was necessary due to the beneficial testimony they had elicited at trial on cross-examination from the government's witnesses. *Id.* at ¶¶ 33, 35, and 40. Furthermore, Dr. Hannon was significantly less experienced and less credentialed than the government's expert biostatistician, Dr. Fleming. *Id.* at ¶ 41. With all of the beneficial testimony that had come out through cross-examination of the government's witnesses, the defense team felt that presenting Dr. Hannon, a significantly weaker biostatistician than the government's biostatistician, "would be worse than calling no witness at all." *Id.* at ¶ 41. They decided to convey these strategic points to Dr. Harkonen and Winchell the following morning. *See id.* at ¶¶ 40-42.

iii. Friday, September 18, 2009: Decision Not to Call Any Defense Experts Made in Consultation With and Approval by Dr. Harkonen and Winchell

Before trial on Friday, September 18, 2009, Topel, Agre, and Moorman met with Dr. Harkonen and Winchell to update them on the case. *Id.* at ¶ 42. Topel told Dr. Harkonen and

Winchell that Dr. Mayer had said he thought the press release was misleading. *Id.* at ¶¶ 40, 42.a. Dr. Harkonen and Winchell agreed that Dr. Mayer could no longer be called to testify as a defense expert witness. *Id.* at ¶ 42.g.

Topel then summarized all of the beneficial testimony that the defense team had elicited on cross-examination of the government's witnesses. *Id.* at ¶ 42.c. Topel explained to Dr. Harkonen and Winchell that his opinion, shared by Agre, Moorman, and Goodman, was that this beneficial testimony obviated the need for defense expert testimony, particularly in light of the risks posed by the government's cross-examination of defense experts. *Id.* at ¶¶ 42.c., 42.f.

Topel told Dr. Harkonen and Winchell that the defense team could ask for a delay in the trial to call Dr. Hannon as an alternative to Dr. Mayer, but that the consensus opinion of Dr. Harkonen's attorneys was that the better strategic decision would be to forego calling Dr. Hannon. *Id.* at ¶ 42.b. Topel explained to Dr. Harkonen and Winchell that Dr. Hannon's lack of experience and credentials, especially when compared to the government's expert, Dr. Fleming, made Dr. Hannon a weak witness for Dr. Harkonen's defense. *See id.* at ¶¶ 18, 36.e., 41. Topel then summarized for Dr. Harkonen and Winchell the risks of calling Dr. Zibrak or any other non-biostatistician expert to testify for Dr. Harkonen's defense, and specifically the risk of having the GIPF-007 clinical trial results admitted at trial. *Id.* at ¶¶ 24, 42.d.; *see supra* Facts Section III.A.4. He also provided the defense team's opinion that, on balance, the testimony of pulmonologists and other experts, including Dr. Katz, provided Dr. Harkonen's defense with little value, particularly when weighed against the risks of their testimony, which he listed for Dr. Harkonen and Winchell. Topel Decl. at ¶ 42.e. To support this position, Topel went through all of the beneficial testimony that Dr. Harkonen's defense team had elicited at trial so far. *Id.* at ¶¶ 33, 42.c. Dr. Harkonen and Winchell agreed that all of the beneficial evidence the defense team had brought out on cross-examination obviated the need to call any other defense witnesses, including Dr. Hannon, Dr. Zibrak, and Dr. Katz. *Id.* at ¶ 42.g.

Later on Friday, September 18, 2009, in a unanimous strategic decision by Topel, Agre, Moorman, Goodman, Dr. Harkonen, and Winchell, the defense rested without calling any defense expert witnesses. *Id.* at ¶ 43.

iv. Defense's Closing Argument

On Wednesday, September 23, 2009, more than six weeks after his opening statement, Topel gave Dr. Harkonen's closing argument. *Id.* at ¶ 44. Before delivering the closing argument, Topel conferred with Agre, Moorman, and Goodman to discuss the strategy for the closing statement. *Id.*

As part of his closing, Topel explained that the defense did not call experts in its case-in-chief because it had gotten the beneficial testimony it needed from the government's experts. *Id.* Topel stated: "Maybe this is a good time for me to remind you that way back at the beginning of the case, when we didn't really know what the evidence in this case, how it was going to be, I told you that we were going to call experts in this case. It turned out that our experts came in through the government's case: Dr. Crager, and by his absence, Dr. Pennington and Dr. Bradford, and certainly Dr. Porter." *Id.*; Trial Transcript at 3672-73. Throughout his closing, Topel recounted much of the beneficial testimony that had been elicited at trial, on cross-examination and on direct. Topel Decl. at ¶ 44.

Topel, Agre, Moorman, and Goodman all agreed that the explanation Topel provided for not calling the defense experts mentioned briefly in opening was sufficient. *Id.* Topel discussed numerous instances of testimony that supported the defense argument that Dr. Harkonen did not have the intent to mislead because he believed the press release was accurate. Trial Transcript at 3627. He highlighted instances in which Dr. Crager and other key doctors at InterMune were supportive of the GIPF-001 clinical trial results, and specifically that the post-hoc subgroup analyses demonstrated a survival benefit. *Id.* at 3661-68. Topel also discussed the patent application for Actimmune, filed before the press release was issued, which contained nearly identical language to the language in the press release that led to Dr. Harkonen's prosecution, which Dr. Harkonen relied upon in believing the assertions in the press release were true. *Id.* at 3679-82. Topel showed that in 2006, years after Dr. Harkonen had left the company, InterMune filed the final clinical study report for the GIPF-001 clinical trial with the FDA, and the company continued to assert that the GIPF-001 clinical trial results demonstrated a survival benefit for Actimmune, without any qualification. *Id.* at 3659-60.

C. Jury Deliberations and Verdict

After a six-week trial, in which eighteen witnesses testified, including six experts, and more than 200 exhibits were admitted, the case was sent to the jury. *Id.* at ¶ 45. The jury deliberated on Thursday, September 24, 2009, Friday, September 25, 2009, and Tuesday, September 29, 2009. *Id.* On the third day of jury deliberations, Tuesday, September 29, 2009, the jury returned a verdict of not guilty on the felony misbranding charge and guilty on the wire fraud charge. *Id.* The defense efforts resulted in Dr. Harkonen being found not guilty on one of the two charges against him. *Id.*

D. Change of Representation

On December 2, 2009, Mark Haddad, of Sidley, filed a Notice of Appearance as counsel for Dr. Harkonen. Doc. 246. Haddad's appearance was in addition to Topel, Goodman, Agre, and Moorman, who, at that point, continued to represent Dr. Harkonen. *Id.* In August 2010, Dr. Harkonen asked the Kasowitz Firm to withdraw as counsel. Doc. 271. On August 25, 2010, Judge Patel granted the Kasowitz Firm's Motion to Withdraw as counsel for Dr. Harkonen. Doc. 272. On October 18, 2010, Judge Patel granted Moorman's Motion to Withdraw as counsel for Dr. Harkonen. Doc. 277.

Haddad was retained by Dr. Harkonen to represent him at sentencing. Haddad filed Dr. Harkonen's Sentencing Memorandum on October 28, 2010. Doc. 288. Haddad filed a Supplemental Sentencing Brief on Loss on February 10, 2011. Doc. 316.

E. Declarations Filed on Behalf of Dr. Harkonen After Trial and Before Sentencing

On October 28, 2010, in support of Dr. Harkonen's Sentencing Memorandum, Haddad filed declarations from Dr. Joseph Zibrak, Dr. Steven Goodman, and Dr. Donald Rubin. He also filed supplemental declarations from Dr. Zibrak and Dr. Goodman on February 10, 2011. None of these declarations offer support for the accuracy of the press release.

Each of Dr. Zibrak's two declarations address aspects of why it is biologically plausible to suppose that interferon gamma-1b would enhance survival in patients with IPF. See Doc. 284 and Doc. 317. In his supplemental declaration, Dr. Zibrak states: "I did not believe the . . . GIPF-001 clinical trial, conclusively proved the efficacy of Actimmune for IPF." Doc. 317. He also states that he no longer prescribes Actimmune to his IPF patients, and insurance companies are reluctant to

pay for Actimmune as a treatment for IPF. Doc. 284.

Dr. Stephen Goodman filed two declarations, on October 28, 2010 and February 10, 2011, in support of Dr. Harkonen's sentencing memoranda. Doc. 282 (hereafter "Dr. Goodman Decl."), Doc. 318 (hereafter "Dr. Goodman Supp. Decl."). Dr. Goodman's supplemental declaration states: "The government's claim that this non-significant result proves the inefficacy of this medication, and therefore that any claim to the contrary is fraudulent (even with correct reporting of the data), is in direct contradiction to the argument made by the government in its brief filed in the *Matrixx* case." Dr. Goodman Supp. Dec. ¶ 5. Dr. Goodman also stated: "P-values below 0.05 are not determinate of truth and P-values over 0.05 are not determinate of falsity." Dr. Goodman Decl. at ¶ 14.

On November 10, 2010, Dr. Harkonen filed a motion for reconsideration with the Court. Doc. 293. Dr. Harkonen's filing states: "that Dr. Goodman's [October 28, 2010] declaration is properly deemed both new and material." *Id.* at 3. Furthermore, Dr. Harkonen stated:

> Dr. Goodman's opinion should also be deemed newly available; it was sought and obtained only after the Order [denying Defendant's Post-Trial Motion to Dismiss the Indictment, for Acquittal, and for a New Trial], *and only after Defendant's exercise of reasonable diligence throughout this prosecution*. *See* N.D. Cal. Local Civ. R. 7-9(1)-(2). *Since the indictment, Defendant's counsel has diligently sought appropriate experts to respond to the government's assertion that the Press Release contains objectively false statements.*

Id. at 4 (*emphasis added*).

In his declaration filed in support of Dr. Harkonen's first Sentencing Memorandum, Dr. Rubin states that the results of the GIPF-001 clinical trial "did not foreclose a reasonable conclusion that Actimmune did provide a survival benefit to IPF patients." Doc. 283 at ¶ 2.

F. New Trial Motions Filed Before Sentencing

While sentencing was pending, Dr. Harkonen, through his attorney Haddad, filed a motion for a new trial on January 7, 2011. Doc. 306. He argued that the Veterans Administration ("VA") documents first produced in November 2010, were suppressed in violation of *Brady v. Maryland*, 373 U.S. 83 (1963). Doc. 306. According to Dr. Harkonen, the internal VA documents showed that the statements made in InterMune's August 28, 2002 press release regarding the GIPF-001 clinical trial results were not material to physicians. *Id.*

On February 11, 2011, Dr. Harkonen also filed a second motion for a new trial pursuant to Federal Rule of Criminal Procedure ("Rule") 33[6] based on newly discovered evidence. Doc. 322. He argued that the amicus brief filed by the government in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) constituted newly discovered exculpatory evidence. Doc. 322.

G. Sentencing

1. Court Denies New Trial Motions.

At Dr. Harkonen's Sentencing on April 13, 2011, the Court heard argument on Dr. Harkonen's two new trial motions. At the hearing, the Court orally denied Dr. Harkonen's new trial motions. On April 18, 2011, the Court issued its written order denying both motions. Doc. 369. The Court denied Dr. Harkonen's motion for a new trial based on the government's withholding of allegedly exculpatory VA documents and *Brady*. *Id.* at 13. The Court found that the "VA documents [held] very little, if any exculpatory value for Harkonen, and taken cumulatively the documents fail to cast any serious doubt as to the materiality of the statements at issue here." *Id.* at 8. The Court noted "the press release was clearly of some influence" on at least one IPF patient and/or his family "who requested that Actimmune be prescribed." *Id.* at 9. The Court further stated: "Moreover, to the extent that patients went so far as to contact members of Congress in order to obtain Actimmune hints at the persuasive influence of some publicly-available information regarding the drug." *Id.*

The Court also denied Dr. Harkonen's motion for a new trial under *Matrixx*. *Id.* at 16. The Court noted that Dr. Harkonen could have looked to a number of factors outside of the GIPF-001 clinical trial results in concluding that Actimmune was an effective treatment for IPF, but did not. *See id.* Instead, Dr. Harkonen's press release included "false statements . . . misrepresenting the results of the GIPF-001 trial." *Id.* The Court stated: "[*Matrixx*] does not mean that statistically insignificant data, on its own, provides a proper basis for substantiating the purported benefits of a drug." *Id.* at 15.

[6] All reference to "rule" or "rules" herein are to the Federal Rules of Criminal Procedure unless otherwise noted.

2. Court Sentences Dr. Harkonen.

On April 13, 2011, Dr. Harkonen's sentence was imposed. As a result of being found guilty on the wire fraud charge against him, Dr. Harkonen was sentenced to three years of probation and a fine of $20,000.00. Doc. 367.

In Sentencing, the Court found that it was unable to determine with a sufficient degree of accuracy that there was a loss as a result of the conduct reflected in the wire fraud count. Sentencing Hearing Transcript at 116. The Court ruled against the government on the issue of loss because the government could not show specific prescriptions were attributable to the press release.

The government conceded that "[t]here is no evidence, the government does not have evidence to show why each individual prescription was written. We have not been able to obtain that evidence, and I don't know if it ever existed, except in the mind of the doctor who wrote the prescription back in 2002." *Id.* at 77. In calculating loss, the government looked at the sales of Actimmune in the aggregate – the total sales, and what happened to the total sales of Actimmune after the press release. *Id.* at 78. The government argued that because GIPF-001 failed, sales should have decreased, but instead they increased, and this increase in sales was due to the fraudulent press release. *Id.* Thus the government's position on actual loss was that if a completely accurate press release had been put out, sales would have at least stopped increasing, if not gone down. *Id.* at 79.

Because the government could not prove which individual prescriptions of Actimmune were caused by Dr. Harkonen's fraudulent press release, the Court found no loss attributable to the press release. The Court noted that "undoubtedly," the press release influenced some people. *Id.* at 117. However, without pointing to specific prescritions that were caused by the press release, the amount of loss was "speculation." *Id.* Therefore, the judge decided to find no actual or intended loss for purposes of sentence enhancement. *Id.*

H. After Sentencing

On April 25, 2011, Dr. Harkonen appealed his conviction to the Ninth Circuit. Doc. 370. On May 12, 2011, the government filed a cross-appeal on Dr. Harkonen's sentence to the Ninth Circuit. Doc. 378.

On August 23, 2011, Dr. Harkonen filed a Complaint for Professional Negligence against

Topel and the Kasowitz Firm concerning their representation of him in his criminal case.[7] *Harkonen v. Topel*, No. 11-513608 (Cal. Super. Ct. Aug. 23, 2011), attached as Exhibit 9.

On March 4, 2013, the Ninth Circuit issued an unpublished decision affirming both Dr. Harkonen's conviction and sentence. *United States v. Harkonen*, No. 11-10242, slip op. (9th Cir. Mar. 4, 2013). Dr. Harkonen then filed a petition for rehearing en banc. On May 7, 2013, the Ninth Circuit denied a petition for a rehearing en banc. Doc. 393. Dr. Harkonen filed a petition for writ of certiorari in the Supreme Court, which was denied on December 16, 2013. Doc. 398.

Dr. Harkonen remained on probation, and thus in custody, until April 13, 2014. *See* Doc. 367 at 2. Dr. Harkonen's Petition for Writ of Error Coram Nobis was filed on July 30, 2014. Doc. 399-1.

ARGUMENT

I. Coram Nobis Requirements

The Ninth Circuit requires a petitioner seeking a writ of coram nobis to prove: (1) a more usual remedy is not available; (2) valid reasons exist for not attacking the conviction earlier; (3) adverse consequences exist from the conviction sufficient to satisfy the case or controversy requirement of Article III; and (4) the error is of the most fundamental character. *United States v. Kwan*, 407 F.3d 1005, 1011 (9th Cir. 2005), *abrogated by Padilla v. Kentucky*, 559 U.S. 356 (2010); *United States v. Walgren*, 885 F.2d 1417, 1420 (9th Cir. 1989) (quoting *Hirabayashi v. United States*, 828 F.2d 591, 604 (9th Cir. 1987)). In order to qualify for this extraordinary relief, a petitioner bears the burden of meeting these four criteria and "[b]ecause these requirements are conjunctive, failure to meet any one of them is fatal." *Matus-Leva*, 287 F.3d 758 at 760 (9th Cir. 2002) (citing *United States v. McClelland*, 941 F.2d 999, 1002 (9th Cir. 1991)).

Given that the common-law writ of error coram nobis is available only when other remedies are not, the situations in which this type of relief has been found to be appropriate are few. The scope of coram nobis is extremely narrow. The writ is an "extraordinary remedy" that should be

[7] This case has been inactive after the filing of the complaint, which was not served on the defendants.

granted "only under circumstances compelling such action to achieve justice." *United States v. Morgan*, 346 U.S. 502, 511 (1954); *see Carlisle v. United States*, 517 U.S. 416, 429 (1996) ("'[I]t is difficult to conceive of a situation in a federal criminal case today where [a writ of coram nobis] would be necessary or appropriate.'") (quoting *United States v. Smith*, 331 U.S. 469, 475 n.4 (1947)). "[J]udgment finality is not to be lightly cast aside" and the use of coram nobis must be limited "so that finality is not at risk in a great number of cases." *United States v. Denedo*, 556 U.S. 904, 911, 916 (2009). "[A]nd courts must be cautious so that the extraordinary remedy of coram nobis issues only in extreme cases." *Id*. at 916. "The Government remains free to argue that respondent's is a merely ordinary case that is not entitled to extraordinary relief." *Id*. Dr. Harkonen's case is not extraordinary and he is not entitled to such relief.

Dr. Harkonen's claim satisfies the first and third requirements for coram nobis relief. [8] An individual no longer in custody is "not eligible for habeas relief or § 2255 relief." *Kwan*, 407 F.3d at 1012. Here, Dr. Harkonen has completed his probation and thus is no longer in custody. Therefore, a more usual remedy is not available.

"There is an 'irrebuttable' presumption that collateral consequences arise from any criminal conviction." *Wood v. Hall*, 130 F.3d 373. Since Dr. Harkonen is challenging his mail fraud conviction, this element of coram nobis is satisfied.

II. Dr. Harkonen Could Have Attacked His Conviction Earlier

Dr. Harkonen is not entitled to coram nobis relief because he does not provide a sound reason why he did not attack his conviction earlier. No statute of limitations applies to coram nobis proceedings; however, petitioners are required to show that "sound reasons exist for failure to seek appropriate earlier relief." *Morgan*, 346 U.S. at 512.

Dr. Harkonen makes several arguments regarding his delay in seeking relief, however, none of those arguments present a valid reason why he did not attack his conviction earlier. Principally, he argues that: (1) he had no way to file a § 2255 motion after the denial of his certiorari petition on

[8] The first and third factors required for coram nobis relief are not at issue in this case. The Petition only addresses in detail the second and fourth requirements for coram nobis relief.

December 16, 2013, and before he completed his probation on April 13, 2014, Doc. 399-1 at 53:15-18; (2) it was costly to mount a collateral attack on his conviction, and his corporate indemnification policy was not extended to cover such an attack, *id*. at 53:21-25; (3) his current counsel could not review relevant materials in time to file a § 2255 motion, *id*. at 54:8-11; and (4) the government delayed him in filing a § 2255 motion, *id*. at 54:16, 17. These reasons, both individually and in combination, do not justify Dr. Harkonen's delay.

A. Dr. Harkonen Could Have Raised His Claim of Ineffective Assistance of Counsel Before Sentencing.

Dr. Harkonen's timeliness argument assumes that the only way to attack his conviction for ineffective assistance of counsel at trial is collaterally, in a § 2255 motion or in a coram nobis petition. He states that the first time he could have raised his claim of ineffective assistance of counsel was in a collateral attack through a § 2255 motion that he could not have filed until the Supreme Court denied his petition for certiorari on December 16, 2013. Doc. 399-1 at 52:5-7.

Contrary to Dr. Harkonen's arguments, he could have attacked his conviction before sentencing. The Supreme Court has recognized that an ineffective assistance of counsel claim may properly be considered on the merits in connection with a properly filed new trial motion in the district court, as indicated in *Strickland v. Washington*, 466 U.S. 668 (1984), the seminal decision on the issue. *See id.* at 697 ("The principles governing ineffectiveness claims should apply in federal collateral proceedings as they do on direct appeal or in motions for a new trial."). In *United States v. Rivera-Sanchez*, 222 F.3d 1057, 1060 (9th Cir. 2000), the Ninth Circuit agreed to hear an ineffective assistance of counsel claim on direct appeal where the "district court held a hearing, prior to sentencing Rivera-Sanchez [the defendant], to examine the question whether [defense counsel] Aguilar's representation was ineffective in order to determine whether a downward departure was warranted on that basis." Both defendant and defense counsel "testified at the hearing regarding Aguilar's efforts to communicate the terms of the proposed plea agreement to Rivera-Sanchez." *Id.* The *Rivera-Sanchez* case shows that courts in this circuit have considered ineffective assistance of counsel claims post-conviction, but pre-sentencing, and that Dr. Harkonen's attorneys at Sidley could have made these arguments before sentencing.

In August 2010, approximately eight months before his sentencing, Dr. Harkonen asked his trial counsel, the Kasowitz Firm to withdraw, which they did on August 25, 2010. Doc. 271 and 272. On October 18, 2010, Moorman withdrew as counsel for Dr. Harkonen. Doc. 277. He retained Mark Haddad of Sidley to replace the Kasowitz Firm and represent him in this case, including at sentencing. Doc. 246. The District Court sentenced Dr. Harkonen on April 13, 2011. Doc. 365. All of the evidence that Dr. Harkonen relies on in his petition to claim ineffective assistance of counsel at trial was known to him months before his sentencing on April 13, 2011. Indeed, on August 23, 2011, Dr. Harkonen sued Topel and the Kasowitz Firm in state court for professional negligence at his trial. Exhibit 9. If Dr. Harkonen knew enough to bring a professional negligence suit in August 2011, he surely could have raised an ineffective assistance of counsel claim before sentencing, especially when everything Dr. Harkonen relies on in his Petition was known to him before sentencing.

Additionally, Haddad filed two motions for a new trial on behalf of Dr. Harkonen before sentencing. Even if Haddad felt that he could not file a new trial motion to pursue Dr. Harkonen's ineffective assistance of counsel claim before sentencing based on the possibility of Haddad becoming a witness in that claim, Doc. 399-1 at 53:12-21, Dr. Harkonen could have hired new counsel to pursue his ineffective assistance of counsel claim against his trial counsel, as he did in August 2011, when he sued Topel and the Kasowitz Firm in state court for professional negligence while Haddad continued to represent Dr. Harkonen on appeal. Exhibit 9.

Since all of the evidence upon which Dr. Harkonen now relies in support of his ineffective assistance of counsel claim was available to him months before sentencing, Dr. Harkonen could have raised this claim in either of his new trial motions or in a third motion, based upon newly discovered evidence found in the expert declarations he filed in support of the two new trial motions, which he filed before sentencing.[9] The District Court had discretion to consider Dr. Harkonen's ineffective

[9] Dr. Harkonen also could have filed a new trial motion before sentencing but after the time for filing in Rule 33 based on excusable neglect due to the Kasowitz Firm's and Moorman's continued representation of him until August 25, and October 18, 2010 respectively. Courts have allowed out-of-time new trial motions alleging ineffective assistance of counsel at trial when the allegedly ineffective trial counsel continues to represent the defendant after the deadline for new trial motions in Rule 33. *United States v. Brown*, 623 F.3d 104, 113 n. 5 (2d Cir. 2010); *see also United States v.*

assistance of counsel claim, to conduct an evidentiary hearing to explore any such allegations, and to dispose of the claim on the merits before or at Dr. Harkonen's sentencing, as the Court did with the two new trial motions that Dr. Harkonen filed before sentencing.

B. Dr. Harkonen Could Have Raised His Ineffective Assistance of Counsel Claim Earlier in a § 2255 Motion.

Alternatively, Dr. Harkonen could have raised his ineffective assistance of counsel claim in a § 2255 motion, while he was still in custody. "Delay is not justified if the petitioner was aware of the potential ground for relief earlier, but did not wish to pursue it." *United States v. Montalvo*, 995 F.2d 234 (9th Cir. 1993). As discussed above, all of the facts that Dr. Harkonen uses in his Petition to support his ineffective assistance of counsel claim were known to him months before his sentencing on April 13, 2011. On August 23, 2011, Dr. Harkonen filed a civil action against Topel and the Kasowitz firm, alleging professional negligence in their representation of Dr. Harkonen at trial. As Dr. Harkonen knew the factual basis for his ineffective assistance of counsel claim and had sued the Kasowitz Firm for malpractice in 2011, Dr. Harkonen could have easily brought his ineffective assistance of counsel claim in a § 2255 motion shortly after the Supreme Court denied his petition for certiorari on December 13, 2013. Although there is no set amount of time that renders error of coram nobis untimely, the Ninth Circuit has denied writs when the defendant fails to offer a legitimate explanation for not raising his challenge earlier. *Kwan,* 407 F.3d at 1013.

Dr. Harkonen failed to file his ineffective assistance of counsel claim for seven months after the Supreme Court denied his petition for certiorari and offers several reasons for his delay. Essentially, Dr. Harkonen argues it was impossible for him to file his ineffective assistance of counsel claim before he did so because it took him at least seven months after the Supreme Court denied certiorari for him to hire counsel to investigate his ineffective assistance of counsel claim and prepare his petition for filing. Doc. 399-1 at 52. Dr. Harkonen's argument ignores the facts that he

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Long, 2012 U.S. Dist. LEXIS 49539, *7-11 (D.S.D. April 9, 2012) (finding excusable neglect where new counsel was not appointed until after time for filing Rule 33 motion; new trial motion based on ineffective-assistance-of-counsel was not filed until the day of sentencing – approximately four months after counsel was appointed).

was well aware of his ineffective assistance of counsel claim years before the Supreme Court denied certiorari and could have hired counsel to investigate this claim and prepare it for filing long before the Supreme Court denied certiorari. While Dr. Harkonen offers multiple reasons for waiting seven months after the Supreme Court's denial of certiorari, there is no reason why Dr. Harkonen could not have prepared his ineffective assistance of counsel claim before the Supreme Court denied certiorari so that he could have filed shortly thereafter.

Lastly, Dr. Harkonen cites *Telink, Inc. v. United States,* 24 F.3d 42, 45 (9th Cir. 1994), for the proposition that the equitable doctrine of laches would apply to a coram nobis action. He refers to *Telink* to affirm that a court can draw on an analogous statute of limitations in determining whether laches may apply. Doc. 399-1 at 50. However, the doctrine of "laches… does not supplant or restate the second *Hirabayashi* requirement," but may be invoked only where the government relies on it as a supplemental defense. *United States v. Riedl,* 496 F. 3d 1003, 1006 (9th Cir. 2007). Thus, unless the government alleges prejudice as a part of the delay prong of coram nobis, laches does not apply. *Id*. The *Riedl* court found that this failure to meet the second element, which was the defendant's burden, does not allow the defendant to shift the initial burden to the government to show laches by showing prejudice from the delay. *Riedl* at 1008-09. Unexplained delay in bringing the petition is not excused if laches cannot be shown. *Id*.

Dr. Harkonen bears the burden of proof to demonstrate there are sound reasons for delay. He has failed to do so. The record shows that Dr. Harkonen had earlier opportunities to attack his conviction with his claim for ineffective assistance of counsel at trial. He could have brought this claim as a motion for a new trial before or at sentencing. He could have raised this ineffective assistance of counsel claim in a motion to vacate, set aside, or correct his sentence pursuant to 28 U.S.C. § 2255, while he was still in custody. Dr. Harkonen has not provided a valid reason why he did not attack his conviction earlier. Thus he has failed to show that his case warrants the exceptional remedy of a writ of error coram nobis.

III. Even Assuming Arguendo that Dr. Harkonen's Ineffective Assistance Claims are Timely, Dr. Harkonen's Four Experienced Trial Attorneys Provided Him Effective Assistance at Trial.

A claimant seeking coram nobis relief "may satisfy the fundamental error requirement by

establishing that he received ineffective assistance of counsel." *Kwan*, 407 F.3d, at 1014. In *Strickland v. Washington*, the Supreme Court set forth the two-part test for evaluating a claim of ineffective assistance of counsel: "First, the defendant must show that counsel's performance was deficient. . . . Second, the defendant must show that the deficient performance prejudiced the defense." 466 U.S. 668, 687 (1984).

"[I]f it is easier to dispose of an ineffectiveness claim on the ground of lack of sufficient prejudice, which we expect will often be so, that course should be followed." *Id.* at 697.

A. The Legal Standard for Measuring Counsel's Performance at Trial

1. Courts Give Great Deference to Counsel's Performance and Presume Their Performance was Reasonable.

The Supreme Court has cautioned against second-guessing counsel's performance, noting "it is all too easy for a court, examining counsel's defense after it has proved unsuccessful, to conclude that a particular act or omission was unreasonable. . . . [C]ounsel is strongly presumed to have rendered adequate assistance and made all significant decisions in the exercise of reasonable professional judgment." *Strickland*, 466 U.S. at 689-90.

In determining the reasonableness of counsel's conduct, the Ninth Circuit states courts "must be 'highly deferential,' avoid 'the distorting effects of hindsight' and 'indulge in a strong presumption that counsel's conduct falls within the wide range of reasonable professional assistance.'" *Smith v. Stewart*, 140 F.3d 1263, 1268 (9th Cir. 1998) (citing *Strickland*, 466 U.S. at 688-89); *see also Yarborough v. Gentry*, 540 U.S. 1, 8 (2003) ("The Sixth Amendment guarantees reasonable competence, not perfect advocacy judged with the benefit of hindsight.") (citations omitted); *Matylinsky v. Budge*, 577 F.3d 1083, 1091 (9th Cir. 2009), *cert. denied*, 130 S. Ct. 1154 (2010) (reviewing court may "neither second-guess counsel's decisions, nor apply the fabled twenty-twenty vision of hindsight") (citation and quotations omitted); *Ainsworth v. Calderon*, 138 F.3d 787, 791, *amended by Ainsworth v. Calderon,* (9th Cir. 1998), *rehearing denied* 152 F.3d 1223 (Sept. 8, 1998) ("Our review is highly deferential; we will not second-guess defense counsel's decisions, but must indulge a strong presumption that his conduct fell within the wide range of professionally competent assistance.").

"When courts are examining the performance of an experienced trial counsel, the presumption that his conduct was reasonable is even stronger." *Chandler v. U.S.*, 218 F.3d 1305, 1316 (11th Cir. 2000) (en banc); *see also Sims v. Brown*, 425 F.3d 560, 581-582, n.14 (9th Cir. 2005), opinion amended, 430 F.3d 1220 (9th Cir. 2005) (noting counsel's extensive experience in finding his performance objectively reasonable).

2. Trial Counsel has a Duty to Make a Reasonable Investigation of the Relevant Laws and Facts.

"[C]ounsel has a duty to make reasonable investigations or to make a reasonable decision that makes particular investigations unnecessary." *Strickland*, 466 U.S. at 691. "[S]trategic choices made after thorough investigation of law and facts relevant to plausible options are virtually unchallengeable . . . ." *Id.* at 690.

Typically, courts have found deficient performance by trial counsel when trial counsel fails to conduct any investigation of reasonable defenses. *Duncan v. Ornoski*, 528 F.3d 1222, 1235 (9th Cir. 2008) (defense counsel's failure to consult a serologist or conduct any investigation regarding potentially exonerating blood evidence was unreasonable); *Luna v. Cambra*, 306 F.3d 954, 961 (9th Cir. 2002) (defense counsel's deficiency not contested by the government on appeal based on "trial counsel's failure to interview and subpoena two alibi witnesses and an exonerating witness"); *Avila v. Galaza*, 297 F.3d 911, 920 (9th Cir. 2002) (defense counsel's decision that certain testimony would not be helpful at trial was improper where counsel failed to conduct an adequate investigation regarding that testimony); *Hart v. Gomez*, 174 F.3d 1067, 1070 (9th Cir. 1999) ("defense counsel's failure to investigate or introduce exculpatory evidence . . . constitutes deficient performance); *Brown v. Myers*, 137 F.3d 1154, 1157 (9th Cir. 1998) (on appeal, defense counsel's deficiency not contested due to "counsel's failure to investigate, and to locate and produce witnesses"); *Showers v. Beard*, 635 F.3d 625, 631 (3d Cir. 2011) (defense counsel "failed to investigate readily available evidence in support of the defense's chosen theory").

3. Courts Defer to Trial Counsel's Strategic Decisions on Whether to Call Expert Witnesses.

The Ninth Circuit is "inclined to defer to counsel's judgment if they made the decision not to

present [] witnesses after interviewing them in person. Few decisions a lawyer makes draw so heavily on professional judgment as whether or not to proffer a witness at trial." *Lord v. Wood*, 184 F.3d 1083, 1095, (9th Cir. 1999). "A lawyer who interviews the witness can rely on his assessment of their articulateness and demeanor - factors we are not in a position to second-guess." *Id.* at 1095 n.8; *see also Sanders v. Trickey*, 875 F.2d 205, 212 (8th Cir. 1989) (choosing to not call a witness at trial is "precisely the sort of strategic trial decision that *Strickland* protects from second-guessing."). The Supreme Court noted that the selection of an expert witness is a model example of the type of "strategic choic[e]" that, when made "after thorough investigation of [the] law and facts," is "virtually unchallengeable." *Hinton v. Alabama*, 134 S. Ct. 1081, 1089 (2014) (quoting *Strickland*, 466 U.S. at 690).

B. Dr. Harkonen's Three Trial Attorneys From the Kasowitz Firm, With the Help of Many Other Attorneys Conducted a Thorough Investigation Before Trial.

Dr. Harkonen's trial team consisted of a core of four experienced attorneys: Topel, Agre, and Goodman from the Kasowitz Firm; and Moorman, a solo practitioner who joined the team a few months before trial. Topel Dec. at ¶ 2; Moorman Decl. at ¶¶ 1-2.

Before trial, Topel, Agre, and Goodman were assisted by many attorneys from multiple firms in preparing for Dr. Harkonen's trial. Topel Decl. ¶¶ 2, 4-5. This defense team conducted a thorough investigation in preparing Dr. Harkonen's defense, including a nationwide search for biostatistics experts, pulmonology experts, and other experts, over the course of more than a year leading up to Dr. Harkonen's trial. *Id.* at ¶¶ 9-23, 25-27.

Finally, Dr. Harkonen has previously admitted that this search was diligent and reasonable. Doc. 293 at 4 ("Since the indictment, Defendant's counsel has diligently sought appropriate experts to respond to the government's assertion that the Press Release contains objectively false statements.").

1. Dr. Harkonen's Defense Team Conducted a Thorough Search for Biostatistics Experts.

Based on the allegations in the indictment, Dr. Harkonen's defense team determined that the key expert issue was whether the press release announcing the GIPF-001 clinical trial results was

false or misleading. Topel Decl. at ¶ 8. Biostatisticians were the type of expert best equipped to interpret the GIPF-001 clinical trial results and determine whether Dr. Harkonen's press release was false or misleading. *Id.*

Beginning in May 2008, Topel, Agre, Goodman, Klasmeier, Kalb, and numerous associates at the Kasowitz Firm began their search for expert biostatisticians to support Dr. Harkonen's defense. *Id.* at ¶¶ 8, 10, 12. The defense team's search for experts started with an initial list of potential experts compiled by Sidley. *Id.* at ¶¶ 4, 10.

Topel, Agre, Goodman, Klasmeier, Kalb, and others conducted an extensive nationwide search for biostatisticians. *Id.* at ¶ 12. From May 2008 until Dr. Harkonen's trial began in August 2009, Topel, Agre, Goodman, Klasmeier, and Kalb were actively scouring the country in an attempt to find any biostatistician willing to support Dr. Harkonen's position that his press release was accurate. *Id.* Agre made trips all over the country in search of biostatisticians to support Dr. Harkonen's defense. *Id.* at ¶¶ 4, 13-16. Klasmeier and/or Kalb accompanied her on some of these visits. *Id.* at ¶¶ 4, 13.b.

Many of the experts that Dr. Harkonen's defense team consulted with did not want to testify in opposition to Dr. Fleming, who was well known and highly regarded as the nation's preeminent expert in biostatistics. *Id.* at ¶ 12. This was particularly true of biostatisticians on the West Coast, as Dr. Fleming was based out of the University of Washington, in Seattle. Furthermore, many biostatisticians were hostile to the idea of supporting Dr. Harkonen's defense. *Id.* at ¶ 11. Even those biostatisticians who were not hostile to the defense still felt that Dr. Harkonen's press release was false or misleading. *Id.*

After a nationwide search by many experienced attorneys over more than one year, Dr. Harkonen's defense team was only able to find two biostatisticians in the entire country who were willing to state that Dr. Harkonen's press release was not false or misleading, Dr. Lawrence Mayer and Dr. Patrick Hannon. *Id.* at ¶ 14.

2. Dr. Harkonen's Defense Team Conducted a Thorough Search for Pulmonology Experts.

In addition to their largely unsuccessful search for biostatisticians willing to support Dr.

Harkonen's defense, the defense team also decided to search for expert pulmonologists. *Id.* at ¶ 19. The search for expert pulmonologists by Dr. Harkonen's defense team began in the early stages of preparing his defense. *Id.* When they initially decided to search for pulmonologists to potentially testify at Dr. Harkonen's trial, Dr. Harkonen's defense team considered four areas where the testimony of an expert pulmonologist may prove useful: (1) explaining the IPF disease; (2) discussing Actimmune's efficacy for treating IPF; (3) noting that pulmonologists were able to read and understand the GIPF-001 clinical trial results stated in Dr. Harkonen's press release without being misled by the press release; and (4) opining that doctors do not rely solely on press releases when making prescribing decisions. *Id.*

Similar to their search for biostatisticians, the search for pulmonologists by Topel, Agre, Goodman, Klasmeier, and Kalb proved difficult. *Id.* at ¶¶ 20-23.

Topel, Agre, and others initially tried to contact some of the pulmonologists on the Steering Committee for the GIPF-001 clinical trial. *Id.* at ¶ 21. The Steering Committee was responsible for the design of the GIPF-001 clinical trial, and it consisted of several highly distinguished pulmonologists regarded as experts on the IPF disease. The defense team's efforts were hindered early on, as Dr. Raghu, the Chair of the Steering Committee, who also was a principal investigator for the GIPF-001 clinical trial was already working with the government, and would serve as a government witness against Dr. Harkonen at trial. *Id.* Dr. Brown, Dr. King, and Dr. Noble were among the expert pulmonologists that the defense team attempted to contact on multiple occasions. *Id.* Of them, Dr. Brown was the only member of the Steering Committee to return a telephone call from Dr. Harkonen's defense team. *Id.*

Dr. Brown left Agre a hostile voice message expressing his disdain and distrust of Dr. Harkonen and the statements in the press release, and he asked her not to contact him again. *Id.* Furthermore, in his message he stated that no one on the Steering Committee would support Dr. Harkonen's defense. *Id.* This disagreement between Dr. Harkonen and those on the Steering Committee for the GIPF-001 clinical trial underscored the dismal outlook for Dr. Harkonen's defense team as they tried to find pulmonologists to support Dr. Harkonen's defense. The Chair of the Steering Committee sided with the government, and the only member of the Committee who

even returned their telephone calls clearly stated his disagreement, and that of his peers, with Dr. Harkonen's press release. *See id.*

As with the search for biostatisticians, the search for pulmonologists was extensive. *Id.* at ¶¶ 20-23. Once again, Agre traversed the country in search of any credible pulmonologist willing to support Dr. Harkonen's defense. *Id.* at ¶ 22. Topel, Agre, Goodman, Klasmeier, Kalb, and others were contacting and conferring with many of the top pulmonologists at some of the most prestigious hospitals in the country, with almost no success. *Id.* At one point Agre and a paralegal from the Kasowitz Firm went so far as to contact 200 pulmonologists from the Actimmune Prescribers list, a list of those pulmonologists who had prescribed Actimmune between October 2000 and September 2001. *Id.* at ¶ 23. Out of those 200 calls, they received only two responses. *Id.*

At the end of this arduous nationwide search for pulmonologists willing to support Dr. Harkonen's defense at trial, the only two pulmonologists willing to testify for Dr. Harkonen's defense were Dr. Zibrak and Dr. Maxfield. *Id.* at ¶¶ 19-23, 25.

3. Dr. Harkonen's Defense Team Conducted a Thorough Search for Other Experts.

Due to the extreme difficulty Dr. Harkonen's defense team had acquiring credible biostatisticians or even pulmonologists willing to support Dr. Harkonen's defense, they were forced to cast a wider net in their search for experts. *Id.* at ¶ 26. As part of their expanded search, Dr. Harkonen's defense team contacted medical experts from other fields and other experts whose expertise was in any way related to Dr. Harkonen's defense. *Id.* Dr. Harkonen's defense team targeted FDA experts, those with expertise monitoring drug companies' communications (like the press release), drug advertising experts, drug promotion experts, off-label marketing experts, and regulatory experts. *Id.* at ¶ 26-27

Once again, Dr. Harkonen's defense team conducted a nationwide search for experts. *Id.* at ¶ 26. Agre and others traversed the country in search for any credible expert, in any relevant field, willing to provide any support Dr. Harkonen's defense. *Id.* at ¶¶ 26-27. Dr. Harkonen's defense team again was met with disappointing results, as many of the experts they contacted felt that the press release was not accurate. *See, e.g.*, *id.* at ¶ 26.b. This extensive search over the course of more

than one year yielded only two other credible experts willing to support Dr. Harkonen's defense, Dr. Zunich and Dr. Katz. *Id.* at ¶¶ 26-27.

The widespread nationwide search for biostatisticians, pulmonologists, and other experts, conducted over more than a year, by Dr. Harkonen's defense team easily satisfies their duty to investigate. *See id.* at ¶¶ 9-23, 25-27. The efforts of five experienced attorneys – Topel, Agre, Goodman, Klasmeier, and Kalb – and numerous other attorneys at the Kasowitz Firm to find experts willing to support Dr. Harkonen's defense can only be described as herculean.

The stunning level of difficulty encountered by Dr. Harkonen's defense team in trying to find biostatisticians, pulmonologists, or other experts willing to support Dr. Harkonen's position can in no way be attributed to any failure to investigate, but instead was clearly a result of Dr. Harkonen's false and misleading press release.

C. Dr. Harkonen's Four Experienced Trial Attorneys Made a Reasonable Strategic Decision Not to Call a Defense Expert Witness at Trial After a Thorough Expert Search and Based on Their Extensive First-Hand Knowledge of Dr. Harkonen's Six-Week Trial.

Heading into trial, Dr. Harkonen's defense team had disclosed six expert witnesses who could potentially testify at Dr. Harkonen's trial: two biostatisticians (Dr. Mayer and Dr. Hannon); two pulmonologists (Dr. Zibrak and Dr. Maxfield); and two other doctors (Dr. Zunich and Dr. Katz). Doc. 117.

All six of these potential defense expert witnesses had been interviewed multiple times, often in person, by members of Dr. Harkonen's defense team. Topel Decl. at ¶¶ 16, 18, 25, 27. The decisions not to call these experts were made unanimously by the four core members of Dr. Harkonen's trial team, Topel, Agre, Goodman, and Moorman, in complete consultation with Dr. Harkonen and his personal criminal attorney, Winchell, who was also present at trial and providing Dr. Harkonen with ongoing advice. ¶ 42.

These four experienced trial lawyers were very familiar with the evidence that had been introduced at trial. *See Chandler*, 218 F.3d at 1316 (with experienced attorneys, stronger presumption conduct was reasonable). The trial was six weeks long and filled with complex testimony and other evidence. The decisions not to call defense experts were based on the defense

team's personal knowledge of the evidence at trial, including all of the beneficial testimony that had been elicited by the defense team through cross-examination and on direct, and their personal knowledge and impressions of the potential defense expert witnesses. *See Hinton*, 134 S. Ct. at 1089 (Expert witness selection is the type of "strategic choic[e]" that is "virtually unchallengeable").

Trial counsel's performance was not deficient because the trial team's cross-examination of the government's witnesses established facts that could have led the jury to conclude favorably on Dr. Harkonen's defense theories that Dr. Harkonen did not have an intent to defraud, and that Dr. Harkonen believed the press release was accurate. *Compare Showers v. Beard*, 635 F.3d 625, 632 (2011) (defense counsel "failed to establish key facts that could have led the jury to find" the defendant's husband had committed suicide, the defense theory in the case).

Dr. Harkonen's trial team provided vigorous representation, and "conducted a skillful cross-examination," in which they "elicited concessions from the State's experts and [were] able to draw attention to weaknesses in their conclusions." *See Harrington v. Richter*, 131 S. Ct. 770, 791 (2011). The trial team received numerous concessions on cross-examination from experts testifying on behalf of the government, including Dr. Crager, Dr. Porter, and Dr. Armstrong, in which they admit that they, and others at InterMune, were using language nearly identical to the charged language in Dr. Harkonen's press release in patent and FDA filings, both at the time of the press release, and years later, long after Dr. Harkonen had left the company. *See* Topel Decl. at ¶ 33.d., f., g. This testimony, along with volumes of other beneficial testimony skillfully elicited by Topel and Moorman, provided the jury with facts necessary to conclude that Dr. Harkonen did not have the intent to defraud because he did not know the press release was not true. *See id.* at ¶ 33.

1. Decision Not to Call Biostatisticians

Dr. Mayer and Dr. Hannon were the only two credible biostatisticians in the entire nation that Dr. Harkonen's defense team was able to find who were willing to support Dr. Harkonen's defense by saying Dr. Harkonen's press release was not false or misleading. Topel Decl. at ¶ 14. On paper, Dr. Mayer clearly was the more impressive of the two. Dr. Mayer had 27 more years of experience as a biostatistician than Dr. Hannon. *See id.* at ¶¶ 15, 18. Dr. Mayer had authored over 70 published articles, and for more than 30 years had taught graduate and undergraduate courses in biostatistics,

advanced statistics, and medicine. *Id.* at ¶ 15. Dr. Hannon's resume noted only one published article and no academic appointments. *Id.* at ¶ 18.

Despite the wide disparity in their qualifications on paper, the defense team interviewed both biostatisticians so that they could form personal opinions of each biostatistician's viability as a defense witness. *Id.* at ¶¶ 16, 18. Agre met twice each with Dr. Mayer and Dr. Hannon in person in early 2009. *Id.* There were also numerous telephone calls and other communications between Dr. Harkonen's defense team and these two experts during that time period. *See id.*

As a result of the review of Dr. Mayer's and Dr. Hannon's credentials and the personal impressions developed from in-person interviews and telephone discussions with both biostatisticians, Dr. Harkonen's defense team determined that Dr. Mayer would make a stronger witness than Dr. Hannon. *See id.* ¶¶ 15-18, 30. In addition to Dr. Mayer's stronger credentials and the stronger impression he made on the defense team, the defense team was also concerned about using Dr. Hannon because of the drastic contrast that would be drawn at trial between the disparities in education, experience, and prestige between Dr. Hannon, and the government's biostatistician, Dr. Fleming. *See id.* at ¶¶ 17-18, 36.e., 41.

As Dr. Harkonen admits in his new trial motion, his counsel conducted a diligent search for experts to testify in his defense. Doc. 293 at 4 ("Since the indictment, Defendant's counsel has diligently sought appropriate experts to respond to the government's assertion that the Press Release contains objectively false statements."). Dr. Harkonen's trial team had a reasonable trial strategy of using Dr. Mayer as the principal biostatistics expert to testify that the press release was accurate in opposition to Dr. Fleming, and leaving Dr. Hannon, a less qualified biostatistician, in reserve to possibly testify in rebuttal to supplement Dr. Mayer's testimony. This reasonable trial strategy was overturned by Dr. Mayer's completely unforeseen and last-minute change in his opinion on the accuracy of the press release. Topel Decl. at ¶ 40. As a result of this last-minute change by Dr. Mayer, the decision by Dr. Harkonen's trial team not to call Dr. Mayer or Dr. Hannon was the most reasonable under the circumstances. *Id.* at ¶¶ 40-41.

i. Dr. Mayer

Dr. Mayer was initially retained by Dr. Harkonen's defense team in February 2009. *Id.* at ¶

16. Beginning in February 2009, members of Dr. Harkonen's defense team met in person or spoke by telephone with Dr. Mayer over twenty times. *Id.* Agre flew to Phoenix twice in March 2009 to meet with Dr. Mayer. *Id.* Dr. Mayer flew to San Francisco to meet with members of Dr. Harkonen's defense team on three occasions, in April 2009, in June 2009, and finally in September 2009, in anticipation of testifying at Dr. Harkonen's trial. *Id.*

Over the entire course of the relationship from February 2009 until Dr. Harkonen's trial, Dr. Mayer consistently supported Dr. Harkonen's position that the press release was not deceptive. *Id.* In fact, on multiple dates, Agre confirmed with Dr. Mayer the statements contained in his expert disclosure, line by line. *Id.* Topel and other members of the defense team also confirmed Dr. Mayer's disclosure with him while preparing him to potentially testify at Dr. Harkonen's trial. *Id.* Dr. Mayer's opinion expressed to members of the defense team was entirely consistent with the statements he approved of in his disclosure: "Dr. Mayer will opine on the accuracy of the statements made in InterMune's August 28, 2002 press release and the fact that none of them is false or misleading. The press release was a true and accurate description of the findings of InterMune's GIPF-001 clinical trial." Doc. 117 at 2; Topel Decl. at ¶ 16.

The meetings and telephone calls between Dr. Mayer and members of Dr. Harkonen's defense team were for the primary purpose of preparing Dr. Mayer to testify at trial. Topel Decl. at ¶ 16. Dr. Mayer explicitly endorsed that the press release was accurate, and the defense team was very comfortable with Dr. Mayer's credentials as an expert biostatistician. *Id.* at ¶¶ 16-17. Judging Dr. Mayer's demeanor and experience, the defense team was also confident in his ability to serve as a strong witness for Dr. Harkonen's defense. *Id.* at ¶¶ 16-17, 31. This opinion was bolstered by all of the time members of the defense team spent with Dr. Mayer, in person or over the telephone, preparing his testimony for trial. *Id.* at ¶ 16. In fact, Dr. Mayer's trial preparation was so in depth that he billed Dr. Harkonen's defense a total of $159,186 for the primary purpose of testifying at trial that Dr. Harkonen's press release was accurate. *Id.*

As they did throughout the trial, Dr. Harkonen's defense team met each day after trial to evaluate the defense's case, including the need to present defense expert witnesses. *Id.* at ¶ 31. While evaluating the defense's case on Wednesday, September 16, 2009, Topel, Agre, and Moorman

recounted all of the evidence that had been elicited from the government's witnesses on cross-examination, and they felt that the evidence presented was sufficient to support the defense team's arguments that the press release was accurate, and that, at a minimum, Dr. Harkonen believed the press release to be accurate, thereby raising more than reasonable doubt as to whether Dr. Harkonen had an intent to defraud. *Id.* at ¶ 35. For these reasons, the defense team felt there was no need to present any defense expert witnesses to prevail at trial, but still planned to call Dr. Mayer because they believed he could help Dr. Harkonen's defense. *Id.* at ¶¶ 35-36.

After trial on Thursday, September 17, 2009, Topel, Agre, Moorman, and Goodman met with Dr. Mayer to prepare his testimony one final time. *Id.* at ¶¶ 38-39. Topel had personally prepared Dr. Mayer several times earlier during this final week of Dr. Harkonen's trial. *Id.* at ¶ 39. At these earlier sessions, as had been the case during the defense team's entire relationship with Dr. Mayer, Dr. Mayer continued to assert that he would testify, that, in his opinion the press release was accurate. *Id.*

However, during this final meeting on September 17, 2009, on the eve of testifying, Dr. Mayer changed his opinion, by now stating that in his opinion the press release might be somewhat misleading. *Id.* This startling flip on the key expert issue in the case was completely unforeseen by Dr. Harkonen's defense team. *Id.* The defense team had met in person and spoke with Dr. Mayer many times since they initially retained him, and at no point before this final meeting did Dr. Mayer give any indication that he believed that Dr. Harkonen's press release might be false or misleading. *Id.*

Topel, Agre, Goodman, and Moorman came to the obvious conclusion that Dr. Mayer could no longer serve as a defense witness because he had flipped on the key expert issue in the case, the accuracy of the press release. *Id.* at ¶ 40. During a meeting before trial on Friday, September 18, 2009, between Topel, Agre, Moorman, Dr. Harkonen, and Winchell, Topel explained to Dr. Harkonen and Winchell that Dr. Mayer had withdrawn his support on the key expert issue of the case, and that the defense team felt this flip meant Dr. Mayer was not a viable defense witness. *Id.* at ¶ 42.a. At that meeting, Dr. Harkonen and Winchell concurred with the defense team's decision that Dr. Mayer could not be a defense witness at trial. *Id.* at ¶ 42.g.

ii. Dr. Hannon

As discussed above, at an early stage in preparing for Dr. Harkonen's trial, Dr. Mayer was chosen by the defense team to serve as the defense's principal biostatistician expert witness because his credentials and perceived demeanor as a witness were determined to be stronger than Dr. Hannon's credentials and demeanor. *See id.* ¶¶ 15-18, 30. This decision resulted from numerous meetings in person and by telephone between the experienced attorneys representing Dr. Harkonen at trial and the two biostatisticians. *See Chandler*, 218 F.3d at 1316 (with experienced attorneys, stronger presumption conduct was reasonable); *see also Lord*, 184 F.3d at 1085 ("inclined to defer to counsel's judgment if they made the decision not to present [] witnesses after interviewing them in person.").

At their meeting after trial on Wednesday, September 16, 2009, Topel, Agre, and Moorman reiterated their opinions regarding Dr. Hannon. *Id.* at ¶ 36.e. At that meeting, they still believed Dr. Mayer was a viable defense witness. *Id.* at ¶ 36.f. Topel, Agre, and Moorman discussed that because of how well cross-examination of the government witnesses went, there was no need to call Dr. Hannon, who was significantly less credentialed and impressive than Dr. Fleming, or even Dr. Mayer. *Id.* at ¶ 36.e.

After Dr. Mayer completely reversed his opinion on the press release at his final meeting with the defense team on Thursday, September 17, 2009, the defense team considered whether it would help Dr. Harkonen's defense to ask for a continuance in the trial to fly Dr. Hannon to San Francisco to have him testify for the defense. *Id.* at ¶¶ 40-41, 42.b. Drawing on their experience as trial attorneys and their personal interactions with Dr. Hannon, Topel, Agre, Moorman, and Goodman, all decided that calling Dr. Hannon at trial, someone who was not as persuasive a witness as Dr. Mayer, and drawing attention to the drastic contrast between the quality of the defense's biostatistician, Dr. Hannon, and the government's biostatistician, Dr. Fleming, "would be worse than calling no witness at all." *Id.* at ¶ 41.

At the meeting before trial on Friday, September 18, 2009, between Topel, Agre, Moorman, Dr. Harkonen, and Winchell, Topel explained to Dr. Harkonen and Winchell that the defense could ask for a continuance and bring in Dr. Hannon to testify for the defense. *Id.* at ¶ 42.b. He

summarized for them why the defense team did not think Dr. Hannon should testify, and recounted all of the beneficial testimony that had been elicited at trial. *Id.* at ¶¶ 33, 42.b. At the end of the meeting, Dr. Harkonen and Winchell agreed that Dr. Hannon should not be called as a witness at trial. *Id.* at 42.g.

The evaluation by the defense team of a potential witness who they had interviewed in person multiple times, considered in the context of all of the testimony and evidence that had already been admitted at trial, was entirely reasonable and precisely the type of strategic decision that the Court should defer to. *See Strickland*, 466 U.S. at 690 ("[S]trategic choices made after thorough investigation of law and facts relevant to plausible options are virtually unchallengeable . . . ."); *see Hinton*, 134 S. Ct. at 1089 (Expert witness selection is the type of "strategic choic[e]" that is "virtually unchallengeable."); *see also Chandler*, 218 F.3d at 1316 (with experienced attorneys, stronger presumption conduct was reasonable).

2. Decision Not to Call Pulmonologists

Dr. Zibrak and Dr. Maxfield were the two credible pulmonologists Dr. Harkonen's defense team found in their extensive nationwide search for experts who were willing to support Dr. Harkonen's defense. Topel Decl. at ¶ 25. The defense team was confident in both doctors' credentials as expert pulmonologists and retained both to potentially testify at Dr. Harkonen's trial, if necessary. *Id.* As trial approached, the defense team decided if one defense pulmonologist was needed, they would use Dr. Zibrak. When they initially decided to search for expert pulmonologists, there were four potential areas the defense team thought the testimony of an expert pulmonologist may prove useful: (1) explaining the IPF disease; (2) discussing Actimmune's efficacy for treating IPF; (3) noting that pulmonologists were able to read and understand the GIPF-001 clinical trial results stated in Dr. Harkonen's press release without being misled by the press release; and (4) opining that doctors do not rely on press releases when making prescribing decisions. *Id.* at ¶ 19.

Based on their continued preparation of Dr. Harkonen's defense leading up to trial, and the evidence and testimony that had been admitted over the course of trial, Dr. Harkonen's four experienced trial attorneys concurred in the decision not to call a defense expert pulmonologist witness. *Id.* at ¶¶ 24, 33, 36.a, b.

i. Dr. Zibrak

Topel, Agre, Goodman, and Moorman relied on their significant experience as trial attorneys in deciding not to call Dr. Zibrak (or Dr. Maxfield) as a defense pulmonologist at Dr. Harkonen's trial. They rightly judged that by the end of the government's case-in-chief, there was little to no benefit in calling a pulmonologist to testify regarding any of the four areas that they initially identified as potentially useful to Dr. Harkonen's defense, and any possible benefit from doing so was far outweighed by the risks associated with calling a defense pulmonologist expert. *Id.* at ¶¶ 24, 36.a, b.

At their after-court meeting on Wednesday, September 16, 2009, Topel, Agre, and Moorman considered whether there was any reason to call a defense pulmonologist witness, and if so, was it worth the risk. *Id.* at ¶ 36.a.

First, Dr. Raghu testified and was cross-examined by the defense regarding the IPF disease. There was nothing for the defense team to gain by having Dr. Zibrak or any other defense pulmonologist testify about the IPF disease. *Id.* at ¶ 36.a.i.

Second, and most importantly, if Dr. Harkonen's defense team called Dr. Zibrak or any other defense pulmonologist to testify that Actimmune was effective for treating IPF, that testimony would likely have opened the door to the GIPF-007 clinical trial results being admitted at Dr. Harkonen's trial. *Id.* at ¶ 36.a.ii. If the GIPF-007 clinical trial results were admitted, the jury would be confronted with powerful evidence that Actimmune – which cost $50,000-$60,000 per year, per patient – was nothing more than "high-priced snake oil." *Id.* at ¶ 24.

Both the government and the defense team knew how strong of an effect the GIPF-007 clinical trial results could have on the outcome of Dr. Harkonen's trial. The defense team knew that the GIPF-007 clinical trial results could become admissible at trial if they "opened the door" to their admissibility. *Id.* at ¶ 36.a.ii.

Testimony by an expert pulmonologist that Actimmune was effective for treating the IPF disease was precisely the type of testimony that could result in the government cross-examining that pulmonologist with the GIPF-007 clinical trial results. *See id.* Additionally, Dr. Zibrak or any other pulmonologist testifying that Actimmune was effective for treating IPF would further have to admit

that they were no longer prescribing Actimune to treat IPF. Doc. 284 at ¶ 7 ("I do not currently prescribe interferon gamma-1b for IPF.").

Third, testimony by Dr. Zibrak or any other pulmonologist that pulmonologists were able to read and interpret clinical trial results in the press release without being misled was of limited value. Topel Decl. at ¶ 36.a.iii. Pulmonologists were not as relevant or valuable as biostatisticians for testifying about the interpretation of clinical trial results. The ability to read and interpret clinical trial results does not make Dr. Harkonen's press release accurate. Testimony about how other pulmonologists would interpret the press release was likely not admissible. Given the limited value of this kind of testimony, and the risk of the GIPF-007 clinical trial results becoming admissible on cross-examination, the potential harm from a pulmonologist's testimony far outweighed its potential value for Dr. Harkonen's defense. *Id.*

Fourth, while Dr. Zibrak could testify that pulmonologists "do not make treatment decisions *solely* on the basis of a press release," this testimony had limited value as it still confirmed the materiality of the press release in that it showed that the press release could influence doctors. Doc. 117 at 8 (*emphasis added*). The government never alleged the press release was the sole basis for a doctor's decision on whether to prescribe Actimmune. There was ample evidence that the press release was material to doctors, Trial Transcript at 2520, 2751-53; Government Trial Exhibits 14, 64, 82, 89, 96, 331, including the common sense notion that a press release announcing that Actimmune helped patients with a fatal disease live longer would influence doctors.[10] Furthermore, similar to Dr. Zibrak's opinions about how other doctors could read and interpret the press release, Dr. Zibrak's opinions about how other doctors made their prescribing decisions likely would not have been admissible. *See* Topel Decl. at ¶ 36.a.iv.

Consequently, there was little value to having Dr. Zibrak or any defense pulmonologist testify at Dr. Harkonen's trial. Based on all of the beneficial evidence elicited at trial, and in their reasoned opinions as experienced trial attorneys, Topel, Agre, Moorman, and Goodman felt the

[10] *See* discussion *infra* Argument Section III.C.2.iii. for further discussion of the materiality of the press release to both doctors and patients.

minimal benefit of defense pulmonologist testimony was significantly outweighed by the risks of cross-examination of any defense pulmonologist witness. *See id.* at ¶ 36.b. At the meeting on the morning of Friday, September 18, 2009, Topel discussed the risks and benefits of calling Dr. Zibrak or any pulmonologist to testify with Dr. Harkonen and Winchell. *Id.* at ¶ 42.d. Dr. Harkonen and Winchell agreed that Dr. Zibrak should not be called to testify and that no defense pulmonologist expert was needed to testify. *Id.* at ¶ 42.g.

Statements from Dr. Zibrak's sentencing declarations further confirm the reasonableness of the defense team's decision not to call Dr. Zibrak at trial. *Id.* at ¶ 36.b. In his second sentencing declaration, Dr. Zibrak stated: "I did not believe the . . . GIPF-001 clinical trial, conclusively proved the efficacy of [Actimmune] for IPF." Doc. 317 at ¶ 15. In his first sentencing declaration, Dr. Zibrak stated: "I was disappointed when I learned the negative outcome of the [GIPF-007 clinical] trial." Doc. 284 at ¶ 30. Zibrak also stated that after the GIPF-007 clinical trial results, insurers became "reluctant to reimburse patients for prescriptions of [Actimmune] (which, at roughly $50,000 to $60,000 per year, is a very expensive drug)." *Id.*

Dr. Zibrak's statement that the GIPF-001 clinical trial did not prove the efficacy of Actimmune as a treatment for IPF contradicts Dr. Harkonen's press release which claims that the same trial proved that Actimmune had a statistically significant survival benefit for IPF patients. Furthermore, the statements in Dr. Zibrak's first sentencing declaration show that Dr. Zibrak was aware of the GIPF-007 clinical trial results, and that he could testify about those results and the other information associated with those results that would damage Dr. Harkonen's defense if they became admissible on cross-examination.

ii. Dr. Maxfield

The above discussion related to Dr. Zibrak (except for Dr. Zibrak's sentencing declarations) applies similarly to Dr. Maxfield. For the same reasons discussed for Dr. Zibrak, Topel, Agre, Goodman, and Moorman made the same reasonable strategic decision not to call Dr. Maxfield or any other defense pulmonologist to testify at trial.

iii. Materiality

Dr. Harkonen argues in his Petition that his trial team could have proven that the press

release was not material by calling Dr. Maxfield or Dr. Zibrak to testify that doctors would not have been influenced by the press release when making prescribing decisions. Doc. 399-1 at 65. Dr. Harkonen's argument fails because it ignores: (1) the government's substantial proof that the press release was material to doctors; (2) the government's substantial proof that the press release was material to patients; and (3) that according to their expert disclosures, Dr. Maxfield and Dr. Zibrak would only have testified that doctors do not rely *solely* on press releases when making prescribing decisions.

a. **Materiality Legal Standard**

Materiality is one of the elements of Dr. Harkonen's wire fraud conviction. The jury instruction at trial regarding materiality stated: "Third, that the statements were material; that is, that they had a natural tendency to influence or were capable of influencing a person to part with money or property. It is not necessary for the government to prove that the scheme was successful, that the defendant actually realized any gain from the scheme, or that an intended victim actually suffered any loss." Trial Transcript at 3553; *U.S. v. Peterson*, 538 F.3d 1064, 1072 (9th Cir. 2008). The "capable of influencing" standard focused on whether the statements "could have influenced" the victim's behavior, not on the victim's "likely behavior" or the probability of the victim being influenced by the statements. *Peterson*, 538 F.3d at 1072.

b. Dr. Harkonen's Press Release was Material to Doctors

There was substantial evidence at trial that Dr. Harkonen's press release was material to doctors. In an August 25, 2002 email between Dr. Harkonen and Weiss, doctors are identified as part of the target audience for the press release (along with "patients, caregivers, and IPF patient family members"). Government Trial Exhibit 14. Furthermore, the press release announced that the GIPF-001 clinical trial results proved that Actimmune helped patients with a fatal disease live longer when the clinical trial results were not otherwise publicly available. Its materiality is obvious.

At trial, the government presented evidence that clearly demonstrated that the press release was material to doctors. InterMune's sales representatives thought that the press release was effective with doctors, as they used the press release to convince doctors to prescribe Actimmune for IPF patients. Trial Transcript at 2520, 2751-53; Government Trial Exhibits 64, 82, 89, 96, 331. On

August 28, 2002, the day the press release was issued, Hann emailed a copy of the press release to the InterMune sales representatives working for her so they could in turn, "email [it] to doctors." Government Trial Exhibit 331. In September 2002, InterMune instructed PHC to draft a cover letter to attach to a copy of the press release and then to widely disseminate those materials to practicing pulmonologists throughout the United States. Trial Transcript at 1118, 1270, 1279-80, 1285; Government Trial Exhibit 6. A voice message from an InterMune sales representative highlighted the effect the press release had on a doctor whom he visited. Government Trial Exhibit 96.

Dr. Harkonen's argument in his Petition that the jury needed expert testimony to figure out if the press release was material, Doc. 399-1 at 65, is contrary to common sense, and the government's overwhelming evidence on materiality presented at trial, including the August 25, 2002 email to Dr. Harkonen stating that the target audience for the press release included doctors and patients.

Dr. Harkonen's Petition argues that expert testimony by Dr. Maxfield and Dr. Zibrak would have shown that the press release was immaterial to doctors. The expert disclosures for Dr. Maxfield and Dr. Zibrak contain the nearly identical statement that each expert "will opine that physicians do not make treatment decisions *solely* on the basis of a press release." Doc. 117 at 4, 8 (*emphasis added*). Instead of proving immateriality, these statements bolster the government's proof that the press release was material to doctors. Because Dr. Maxfield and Dr. Zibrak both qualify their statements with the term "solely," it can easily be inferred that a press release is among the factors capable of influencing a doctor's prescribing decisions.

The evidence at trial clearly demonstrated the press release was material to doctors. Dr. Maxfield and Dr. Zibrak could not have substantially assisted Dr. Harkonen's defense on this issue. It was entirely reasonable for Dr. Harkonen's trial team to decide to forego calling Dr. Maxfield and Dr. Zibrak as witnesses at trial.

c. Dr. Harkonen's Press Release was Material to Patients

Dr. Harkonen's arguments that his trial team should have called Dr. Maxfield and Dr. Zibrak as experts at trial to disprove the materiality of the press release is also defeated by the government's proof at trial that the press release was material to patients. As with doctors, the August 25, 2002 email between Weiss and Dr. Harkonen identifies patients and IPF patient family members as part of

the target audience for Dr. Harkonen's press release. Government Exhibit 14.

Similar to the request for dissemination of the press release to doctors, InterMune instructed PHC to send out a letter to patients discussing the GIPF-001 clinical trial results as reported in the press release. Trial Transcript at 1281. On September 19, 2002, PHC started sending a letter to patients, describing the GIPF-001 clinical trial results as reported in the press release. Government Trial Exhibits 7, 134. InterMune's request to send marketing materials related to the press release to patients was further evidence that InterMune considered patients a decision-making group regarding the decision to take Actimmune to treat IPF, and they believed their efforts in targeting patients with the press release would be capable of influencing patients' decisions. Finally, the materiality of the press release to IPF patients suffering from a fatal disease is obvious.

In denying Dr. Harkonen's motion for a new trial, Judge Patel identified patients as part of "the universe of decision-makers against whom the materiality inquiry should be measured." Doc. 369 at 8. The government's indictment of Dr. Harkonen specifically included patients as a group targeted by Dr. Harkonen's press release. Doc. 1 at ¶ 24 ("It was an essential part of the scheme to defraud that the information in the press release be conveyed to pharmacies that sold Actimmune and to patients and doctors."). The VA documents included a letter to the son of an IPF patient that showed the press release had the capability to influence a "patient and/or his son, who requested Actimmune be prescribed." Doc. 369 at 9. Two other VA documents were responses to inquiries from "members of Congress regarding why their constituents were unable to receive Actimmune." *Id.* at 2. ". . . [T]o the extent that patients went so far as to contact members of Congress in order to obtain Actimmune hints at the persuasive influence of some publicly-available information regarding the drug." *Id.* at 9.

The Doctor Tapes mentioned in the Petition offer further evidence that patients were part of the decision-making universe regarding whether to seek out and take Actimmune to treat IPF. At the November 5, 2002 CHEST conference in San Diego, several expert pulmonologists stated that patients are a large part of the decision-making process. Dr. Raghu stated: "I sit with the patient and talk it over in terms of the disease that is concerned, and give him or her the options, and have the patient come into the partnership in terms of the decision-making and proceed in terms of treatment.

. . . And then leave it up to the patient to decide what they think is the best to do given the data that we presently have. " WOOD-MEDIA-0010 at 1:10-2:00. Dr. Tino stated: ". . . I sit down with the patients, and I show them the data, and I plan on showing them the data." *Id.* at 3:15-4:15. Dr. Schwarz stated: ". . . I certainly discuss [the GIPF-001 clinical trial data] with every patient that I see." *Id.* at 4:15-5:40.[11]

Contrary to Dr. Harkonen's argument that only doctors decide what drugs a patient will take, patients can seek out a drug or refuse to take a drug even when it is prescribed. Any potential testimony from Dr. Maxfield or Dr. Zibrak would have had no effect on the government's substantial evidence that the press release was material to patients. The reasonableness of the decision by Dr. Harkonen's trial team to forego calling Dr. Maxfield and Dr. Zibrak is further supported by their inability to testify on the press release's materiality to patients.

3. Decision Not to Call Other Experts

Due to the difficulty the defense team had finding expert biostatisticians and expert pulmonologists willing to support Dr. Harkonen's defense, his attorneys conducted a nationwide search for other credible experts that would potentially be relevant to supporting Dr. Harkonen's defense. The only other potentially relevant and credible experts they were able to retain for Dr. Harkonen's defense were Dr. Zunich and Dr. Katz.

i. Dr. Zunich

Dr. Zunich is a medical doctor and an expert in medical and regulatory affairs, specifically as they relate to clinical trials. Topel Decl. at ¶ 27.a. Dr. Harkonen's defense team retained Dr. Zunich to testify that the GIPF-001 clinical trial was a well-developed and well-conducted clinical trial. *Id.* Dr. Zunich did not have the necessary expertise in interpreting clinical trial results to testify as a defense expert opposing Dr. Fleming regarding the accuracy of the press release's interpretation of those results. *Id.* Since it was undisputed at trial that the GIPF-001 clinical trial was properly

[11] These statements further reinforce the reasonableness of the decision by Dr. Harkonen's trial team to forego any attempt to use the Doctor Tapes at trial. *See* discussion *infra* Argument Section III.E. These statements would have supported the government's proof that the press release was material to patients.

designed and conducted, there was no need for Dr. Zunich's testimony, and it would have been of no value to Dr. Harkonen's defense. *Id.* at ¶ 36.c. Topel's, Agre's, Moorman's, and Goodman's decision to forego calling Dr. Zunich to testify at trial was entirely reasonable.

ii. Dr. Katz

Dr. Katz is a medical doctor who told the defense team that he believed the press release was accurate. *Id.* at ¶ 27.b. During their meeting on Wednesday, September 16, 2009, Topel, Agre, and Moorman evaluated whether it would be useful to call Dr. Katz as a defense witness. *Id.* at ¶ 36.d. Dr. Katz was not a biostatistician, or even a pulmonologist, so he clearly lacked the credentials or experience needed to testify as a defense expert interpreting the GIPF-001 clinical trial results in opposition to Dr. Fleming. *Id.*

Dr. Katz's value was that he had a likeable demeanor and could explain medical issues in terms that would be simple for the jury to understand. *Id.* at 27.b. The defense team believed it would be useful to have a witness like Dr. Katz, with an excellent demeanor and great communication skills, to more clearly explain to the jury Dr. Mayer's interpretation of the GIPF-001 clinical trial results. *Id.* Since Dr. Katz's value to Dr. Harkonen's defense was directly tied to Dr. Mayer, once Dr. Mayer withdrew his support for the accuracy of the press release, Dr. Katz was of little value to the defense team. *Id.* at ¶ 36.d.

At the Friday, September 18, 2009 meeting with Dr. Harkonen and Winchell, Topel explained that Dr. Katz lacked the credentials necessary to oppose Dr. Fleming in interpreting the GIPF-001 clinical trial results, as he was not a biostatistician or pulmonologist; nor did he treat IPF patients. *Id.* at ¶ 42.e. Topel further explained that as the defense team, including Dr. Harkonen and Winchell, had decided Dr. Mayer would not serve as a defense witness, it was no longer possible to call Dr. Katz to explain Dr. Mayer's testimony to the jury. *Id.* Dr. Harkonen and Winchell agreed with the defense team's decision not to call Dr. Katz as a defense witness. *Id.* at ¶ 42.g.

Every decision made by Topel, Agre, Moorman, and Goodman to rest Dr. Harkonen's case at trial without calling Dr. Mayer, Dr. Hannon, Dr. Zibrak, Dr. Maxfield, Dr. Zunich, and Dr. Katz was strategic, based on the considerable insight of these four experienced trial attorneys. Members of the defense team met in person and spoke with every one of these witnesses. Through these multiple in-

person meetings and telephone calls, Dr. Harkonen's experienced defense team was able to evaluate the quality of these witnesses, and they were in the best position to determine the risks and benefits of each witness's potential testimony. The ultimate decisions not to call these witnesses only came near the end of a six-week trial, filled with complicated evidence. Even in hindsight, their decisions not to call these expert witnesses are entirely reasonable. *Lord*, 184 F.3d at 1985 (Ninth Circuit "inclined to defer to counsel's judgment if they made the decision not to present [] witnesses after interviewing them in person); *Hinton*, 134 S.Ct. at 1089 (selection of expert witness after a thorough investigation is "virtually unchallengeable") (quoting *Strickland*, 466 U.S. at 690).

D. The Trial Team's Decision Not to Call the Expert Witnesses Briefly Mentioned in Opening Was Explained in Closing and Entirely Reasonable.

1. Legal Standard

Many facts are relevant to whether defense counsel was ineffective for failing to call witnesses mentioned in the opening statement. A determination that counsel was ineffective for failure to produce a promised witness "is necessarily fact based. '[N]o particular set of rules can be established to define effective assistance....' " *U.S. v. McGill*, 11 F.3d 223, 227 (1st Cir. 1993) (quoting *United States v. Natanel*, 938 F.2d 302, 310 (1st Cir. 1991), *cert. denied*, 502 U.S. 1079 (1992)).

Among the many relevant facts that courts will look to in evaluating a failure to call a witness mentioned in opening are the following: (1) whether defense counsel explained the failure, *see Williams v. Woodford*, 859 F.Supp.2d 1154, 1167 (E.D.Cal. 2012) ("jury will draw negative inferences from the *unexplained* absence of . . . promised testimony") (*emphasis added*); *see also Hampton v. Leibach*, 347 F.3d 219, 259 (7th Cir. 2003); *Anderson v. Butler*, 858 F.2d 16, 17 (1st Cir. 1988); (2) how much did defense counsel discuss the witness in opening or later at trial, *Schlager v. Washington*, 887 F.Supp. 1019, 1027 (N.D. Ill. 1995); (3) whether defense counsel's opening was before the government's case-in-chief, *id.* at 1026-27; *see also Anderson*, 858 F.2d at 18; (4) how much time passed between defense counsel's opening and the end of the defense's case-in-chief, *see U.S. v. Crawford*, 680 F.Supp.2d 1177, 1202 (E.D.Cal. 2009) (Any potential danger from promises in the opening statement "was minimized and dissipated by the significant temporal

gap of over six weeks between the opening statements and the close of evidence."); *see also Schlager*, 887 F.Supp. at 1026-27 (The passage of time between defense counsel's opening statement and the defense putting on its case allows defense counsel "an opportunity to reevaluate" the decision to have promised experts testify.); and (5) whether defense counsel's failure to call the witness mentioned in opening was due to unforeseeable developments at trial, *Ouber v. Guarino*, 293 F.3d 19, 29 (1st Cir. 2002) ("Unexpected developments sometimes warrant changes in previously announced trial strategies. . . . [W]e cannot fault counsel for not guarding against the unforeseeable . . . .").

2. Topel's Decision Not to Call Witnesses Mentioned in Opening was Reasonable

On August 18, 2009, as a very small part of his opening statement, given before the government's case-in-chief, Topel very briefly mentioned that the defense would have three experts testify on Dr. Harkonen's behalf at trial, Dr. Mayer, Dr. Zibrak, and Dr. Katz. Trial Transcript at 324-25. Topel spent the bulk of his opening statement on behalf of Dr. Harkonen discussing the numerous avenues by which the defense team would challenge the government's case against Dr. Harkonen, including that Dr. Harkonen had no intent to defraud because he believed the press release was true. Topel never mentioned Dr. Mayer, Dr. Zibrak, or Dr. Katz by name in front of the jury after his opening statement and did not discuss defense experts again after this brief mention in opening until explaining their absence in closing. The defense rested over five weeks after Topel's opening. Topel gave his closing on behalf of Dr. Harkonen over six weeks after his opening.

First, Topel explained the failure to call witnesses promised in opening. In closing Topel stated: "Maybe this is a good time for me to remind you that way back at the beginning of the case, when we didn't really know what the evidence in this case, how it was going to be, I told you that we were going to call experts in this case. It turned out that our experts came in through the government's case: Dr. Crager, and by his absence, Dr. Pennington and Dr. Bradford, and certainly Dr. Porter." Trial Transcript at 3672-73.

During closing, Topel recounted testimony from numerous government witnesses that supported the defense theory that Dr. Harkonen did not have the intent to mislead because he believed the press release was accurate. *Id.* at 3627. The evidence that Topel and Moorman

obtained on cross-examination of the government's witnesses was more than sufficient to support Dr. Harkonen's defense on this issue. *See* Topel Decl. at ¶ 33. Topel highlighted testimony that showed Dr. Crager, InterMune's Chief Biostatistician, and other key doctors at InterMune were positive about the GIPF-001 clinical trial results, and agreed that there was a demonstrated survival benefit for Actimmune in treating IPF. Trial Transcript at 3661-68. Topel discussed the continued use by others at InterMune – both around the time of the press release, and for years to come, long after Dr. Harkonen had left the company – of nearly identical language to that language for which Dr. Harkonen was being prosecuted. Thus, Topel's explanation to the jury for not calling the witnesses mentioned in opening was reasonable and solidly based on the evidence at trial.

Second, Topel's only mention of defense experts in the presence of the jury was the brief mention of Dr. Mayer, Dr. Zibrak, and Dr. Katz in opening. This one brief mention of these witnesses in a six-week trial could hardly constitute deficient performance. *Schlager*, 887 F.Supp. at 1027; *compare Williams v. Woodford*, 859 F.Supp.2d at 1157 (Trial counsel continuously stated to the jury defendant would testify, while at the same time persuading defendant not to testify.).

Third, Topel's mention of defense experts came prior to the government's case-in-chief. As Topel explained in closing, he mentioned these witnesses before he knew what the government's evidence would be. The beneficial evidence from cross-examination of the government's expert witnesses certainly justified not calling the experts whom Topel mentioned in opening, again as he explained in closing. *See Schlager*, at 1026-27 (passage of time between defense counsel's opening statement and putting on the defense's case-in-chief allows defense counsel "an opportunity to reevaluate" the decision to have promised experts testify); *see also Anderson*, 858 F.2d at 18.

Fourth, more than five weeks had passed between Topel's mention of the experts in opening and the end of Dr. Harkonen's case-in-chief. This long gap between the mention of these experts in opening and the defense's case-in-chief permitted Dr. Harkonen's trial team to re-evaluate whether these witnesses were needed. *See U.S. v. Crawford*, 680 F.Supp.2d 1177, 1202 (E.D.Cal. 2009) (Any potential danger from promises in the opening statement "was minimized and dissipated by the significant temporal gap of over six weeks between the opening statements and the close of evidence."); *see also Schlager*, 887 F.Supp. at 1026-27.

Fifth, Topel's decision not to call Dr. Mayer, Dr. Zibrak, or Dr. Katz was due to unforeseen developments and the changing strategy that was developed as a result of these unexpected circumstances. *See* Topel Decl. at ¶ 39 (on the eve of testifying, Dr. Mayer tells Dr. Harkonen's trial counsel the press release is somewhat misleading). After many in-person meetings and telephone discussions with Dr. Mayer, during which Dr. Mayer always stated he believed the press release was accurate, it was completely unforeseen that Dr. Mayer would withdraw his support on that very issue on the eve of testifying. *See Ouber*, 293 F.3d at 29 (". . . [W]e cannot fault counsel for not guarding against the unforeseeable . . . .").

Topel did not know what evidence would come out during the government's case-in-chief. Topel Decl. at ¶ 30. Based on the state of the evidence at the end of the government's case-in-chief, Dr. Zibrak's testimony had minimal value but posed great risk to Dr. Harkonen's defense. *See State v. Eby*, 342 So.2d 1087, 1089 (Fla. Dist. Ct. App. 1977) (risks of testimony of witnesses promised at opening can strategically weigh on decision not to call those witnesses); *see also* discussion *supra* Argument Section III.C.2.i.

Because Dr. Katz's role was to explain Dr. Mayer's expert opinion, the value of Dr. Katz's testimony was intimately tied to calling Dr. Mayer as a witness. *See* Topel Decl. at ¶ 27.b. As Dr. Mayer had changed his opinion on the key expert issue, the accuracy of the press release, the defense team rightly felt that Dr. Katz's testimony, on its own, offered no benefit to Dr. Harkonen's defense. *Id.* at ¶ 42.e. The defense team cannot be faulted for Dr. Mayer's last minute change of opinion, which rendered Dr. Katz's testimony of little value to Dr. Harkonen's defense. *See Ouber*, 293 F.3d at 29.

Ultimately, four experienced trial attorneys who were present at trial and familiar with the testimony and evidence presented agreed there was no need to call defense experts and that Topel's explanation in closing for not calling the experts mentioned in opening was reasonable and sufficient.

E. Counsel Was Not Deficient for Failing to Use the Doctor Tapes

Dr. Harkonen alleges that his counsel was deficient for failing to review and use tapes containing pulmonologists discussing the GIPF-001 clinical trial results from the ERS and CHEST

medical conferences, and a presentation by Dr. Nathan.[12]

Dr. Harkonen's defense team reviewed these tapes at least twice before Dr. Harkonen's trial. Topel Decl. at ¶¶ 46-47. After multiple reviews of the tapes by attorneys at the Kasowitz Firm, Topel, Agre, and Goodman rightly judged that the content on the tapes ranged from irrelevant to harmful to Dr. Harkonen's defense. *Id.* at ¶¶ 48-49. The tapes do not support a statistically significant survival benefit as asserted by Dr. Harkonen in the press release. Even summaries of the tapes written by Dr. Harkonen's counsel at sentencing and included in Dr. Harkonen's Petition do not state that the GIPF-001 clinical trial results demonstrated a survival benefit. *See* Doc. 399-1 at 40, 43.

1. ERS Conference Tapes.

At the ERS conference on September 18, 2002, Dr. Paul Noble discussed the GIPF-001 clinical trial results. INR-MEDIA-0034. While Dr. Noble called the results "important," and made other positive statements about the GIPF-001 clinical trial results, he never stated that the GIPF-001 clinical trial results proved or showed a statistically significant survival benefit as written in the press release. Dr. Noble also undermined the accuracy of the press release by stating that using the 55% FVC as a cut-off for subgroup analysis of the GIPF-001 clinical trial results, as the press release did, would be subject to criticism. *Id.* at 33:40-34:43.

While generally positive about the GIPF-001 clinical trial results, ultimately, since Dr. Noble's statements on the ERS tapes do not support the press release's overstatement of those results and criticize the subgroup analysis used in the press release, the defense team's decision not to introduce the ERS tapes with quotes from Dr. Noble was reasonable. *See* Topel Decl. at ¶ 48.b. Additionally, the defense team contacted Dr. Noble on multiple occasions to see if he would be willing to serve as a witness for Dr. Harkonen's defense, but Dr. Noble did not return their phone calls. Id. at ¶ 49.

[12] The Petition quotes a summary created by Sidley regarding Dr. Noble's presentation at the ERS Conference, which was part of Dr. Harkonen's Supplemental Sentencing Brief on filed on February 10, 2011, rather than Dr. Noble's actual statements at that conference. Doc. 399-1 at 40; Doc. 316 at 13-14.

2. CHEST Conference Tapes.

At the CHEST conference in San Diego on November 5, 2002. Dr. Noble noted the data was "compelling." WOOD-MEDIA-0010 at 2:10-3:15. Dr. Tino stated: "I'm disappointed that I don't think the study definitively answered the question of interferon gamma's efficacy of the disease," and his "hypothesis was that if the drug is going to work it's going to work in patients with mild or to moderate disease." *Id.* at 3:15-4:15. Dr. Schwarz noted that while there "appears to be a survival benefit . . . as everybody has alluded to we need more time. . . . My feeling is, I certainly discuss [the GIPF-001 clinical trial data] with every patient that I see." *Id.* at 4:15-5:40.

Dr. Noble's statement that the GIPF-001 clinical trial data was "compelling" is irrelevant and does nothing to establish that Dr. Harkonen's press release was accurate. Dr. Tino's statement questioned Actimmune's efficacy in treating the IPF disease, directly contradicts the press release's conclusion that the GIPF-001 clinical trial results showed a statistically significant survival benefit, and was damaging to Dr. Harkonen's defense. Similarly, Dr. Schwarz's statement was harmful to Dr. Harkonen's defense because it alluded to the ambiguity in the GIPF-001 clinical trial results, and uncertainty as to whether there was a survival benefit. Agre and others on the defense team contacted doctors on the tapes, including Dr. Noble and Dr. Schwarz, but no one returned their calls.

The defense team's decisions not to introduce statements from the CHEST conference tapes were entirely reasonable, as the statements range from irrelevant to harmful to Dr. Harkonen's defense. Furthermore, Agre and others on the defense team contacted doctors on the tapes, including Dr. Noble and Dr. Schwarz, but no one returned their calls.

3. Presentation of Dr. Steven Nathan.

The Petition also cites a presentation by Dr. Steven Nathan, INR-MEDIA-0057, in which he analyzes the GIPF-001 clinical trial results, for the "fallacy of using the primary endpoint as the sole determinant of the study's success or failure." Doc. 399-1 at 42. This statement is irrelevant to this case because the GIPF-001 clinical trial failed not only on its primary endpoint, but it also failed to reach statistical significance on any of its secondary endpoints.

At no point does Dr. Nathan state there was a statistically significant survival benefit and many of Dr. Nathan's statements on the tape are damaging to Dr. Harkonen's defense. Dr. Nathan

stated: "The study failed to meet its primary endpoint and in that regard is a negative study." INR-MEDIA-0057 at 13:58-14:05. Later in his presentation and discussion, Dr. Nathan said the "results of [the] study [were] controversial to say the least." *Id.* at 17:33-17:37. During his presentation, two physicians called in to Dr. Nathan to question the results of the GIPF-001 clinical trial, sharing the same criticism that Dr. Fleming and Dr. Walton had – that because there was no meaningful physiological improvement, *i.e.*, improvement in lung function, there was no evidence Actimmune was effective in treating IPF. *Id.* at 43:06-45:15, 55:45-1:01:30. Dr. Nathan agreed that he would have expected improvement in lung function to occur before the improvement in survival. *Id.* at 44:28-44:38. He noted the study raised a lot of questions. *Id.* at 44:40-44:45.

Dr. Nathan's presentation would not have helped Dr. Harkonen's defense because Dr. Nathan acknowledged the results are controversial, that the primary endpoint and all secondary endpoints were missed, including survival, and he did not have any explanation for the lack of improved lung function in patients taking Actimmune. Instead, he agrees that he would expect to see improvement in lung function along with improvement in survival, and yet there was no improvement in lung function. Nothing Dr. Nathan says supports the press release's conclusion that the GIPF-001 clinical trial results showed a statistically significant survival benefit. The government could have used Dr. Nathan's negative statements about the GIPF-001 clinical trial results to bolster its proof at trial that the GIPF-001 clinical trial results were ambiguous, and that Dr. Harkonen should not have been drawing definitive conclusions from the data.

Dr. Harkonen's defense team's decision not to use Dr. Nathan's presentation at trial was reasonable and is amply supported by Dr. Nathan's statements highlighting the missed endpoints in and ambiguous nature of the GIPF-001 clinical trial results, as well as the lack of improved lung function which is inconsistent with any possible survival benefit.

4. The Doctor Tapes are Inadmissible Hearsay.

In addition to all of the substantive reasons that the defense team chose not to use these tapes at Dr. Harkonen's trial, the tapes are inadmissible hearsay evidence. Fed. R. Evid. 802. At trial, Dr. Harkonen's trial team would have had to call the pulmonologists speaking on the tapes so they could explain their opinions in person at trial.

Dr. Raghu was one of the featured speakers on the tapes referenced in Dr. Harkonen's Petition. Dr. Raghu testified as a government witness at Dr. Harkonen's trial. *See* Topel Decl. at ¶ 21. Other speakers on the tapes included Dr. Noble and Dr. Schwarz. On multiple occasions the defense team tried to contact these pulmonologists and others to see if they would be willing to serve as witnesses for Dr. Harkonen's defense. *Id.* at ¶ 49. The speakers on the tapes whom the defense team contacted did not return the defense team's telephone calls. *Id.* Without the speakers on the tapes willing to testify, the tapes by themselves are inadmissible hearsay. Finally, even if these speakers were willing to testify at Dr. Harkonen's trial, there is no indication that these doctors would have testified in 2009 similarly to their 2002 statements on the tapes, especially in light of the failed GIPF-001 clinical trial.

IV. Prejudice

Even if the Court were to find that Dr. Harkonen's defense counsel rendered deficient performance, Dr. Harkonen still should not prevail on his claim of ineffective assistance of counsel because he was not prejudiced by counsel's performance. Nothing that is alleged in Dr. Harkonen's Petition creates a reasonable probability that the outcome of Dr. Harkonen's trial would have been any different.

A. Legal Standards for Prejudice

Under the second prong of *Strickland*, the defendant must show that "counsel's errors were so serious as to deprive the defendant of a fair trial, a trial whose result is reliable." *Strickland*, 466 U.S. at 687. "Even if a defendant shows that particular errors of counsel were unreasonable, therefore, the defendant must show that they actually had an adverse effect on the defense. . . . The defendant must show that there is a reasonable probability that, but for counsel's unprofessional errors, the result of the proceeding would have been different. A reasonable probability is a probability sufficient to undermine confidence in the outcome." *Id.* at 693-94. When conducting the prejudice inquiry, a court must consider counsel's error in the context of "the totality of the evidence before the judge or jury." *Strickland*, 466 U.S. at 695. To satisfy the prejudice prong of *Strickland*, "[t]he likelihood of a different result must be substantial, not just conceivable." *Harrington v. Richter*, 131 S. Ct. 770, 791–92 (2011).

Defendant is not prejudiced by the failure to present testimony or evidence where the value of that evidence is mere speculation, or potentially inculpatory. *Rice v. Hall*, 564 F.3d 523, 525-26 (1st Cir. 2009) (finding of prejudice cannot rest on "'mays' and 'could haves'").

B. Dr. Harkonen was Not Prejudiced by Trial Counsel's Performance Because His Petition Does Not Offer Any Evidence that Undermines the Confidence in the Outcome of His Trial.

Dr. Harkonen's defense was not undermined by his trial team's decision not to call expert witnesses because their testimony was not clearly beneficial to Dr. Harkonen. The experts available to Dr. Harkonen's trial team were either unhelpful or carried significant risks of damaging his defense if they testified. *See Rice*, 564 F.3d at 525-26 (no finding of prejudice if value of the evidence is mere speculation or potentially inculpatory).

Trying to assess the impact of expert testimony in such a long and complicated trial is inherently speculative. This is especially so when there are obvious risks for damaging testimony on cross-examination of the expert. *See id.* Consequently, Dr. Harkonen suffered no prejudice even if his trial team was deficient in failing to call these witnesses.

1. Dr. Harkonen Was Not Prejudiced by the Decision Not to Call Defense Biostatisticians.

The key issues at Dr. Harkonen's trial were whether the press release was false or misleading, and whether Dr. Harkonen had an intent to defraud, which centered on whether Dr. Harkonen believed the press release was accurate. As a result of an extensive search for more than one year, conducted by five experienced trial attorneys and numerous other associates, the defense team was only able to find two biostatisticians willing to state the press release was accurate: Dr. Mayer and Dr. Hannon. Topel Decl. at ¶ 14. Dr. Harkonen has previously admitted that this search was diligent and reasonable. Doc. 293 at 4 ("Since the indictment, Defendant's counsel has diligently sought appropriate experts to respond to the government's assertion that the Press Release contains objectively false statements."). Because Dr. Mayer, the principal defense biostatistics expert, changed his opinion about the press release without warning on the eve of testifying, Dr. Harkonen's team could not call him or Dr. Hannon. Topel Decl. at ¶¶ 39-41. Consequently, Dr. Harkonen was not prejudiced in any way by the defense team's decision not to call Dr. Mayer or Dr.

Hannon. Furthermore, no other biostatistician mentioned in Dr. Harkonen's Petition could have provided beneficial testimony at Dr. Harkonen's trial.

i. Dr. Mayer

As discussed above, on the eve of testifying and without warning, Dr. Mayer withdrew his support of Dr. Harkonen's defense and stated that the press release might be somewhat misleading. *Id.* at ¶ 39. This change was unforeseen and could not have been anticipated by Dr. Harkonen's defense team. *Id.* The defense team had confirmed Dr. Mayer's opinion that the press release was accurate many times previously, both in-person and over the telephone. *Id.*

It clearly would have severely damaged Dr. Harkonen's defense to allow Dr. Mayer to take the stand as a defense witness and testify that he thought the press release was misleading. Dr. Harkonen suffered no prejudice from his trial team's decision not to call Dr. Mayer.

ii. Dr. Hannon

The decision not to call Dr. Hannon as a defense expert witness also did not undermine the outcome of Dr. Harkonen's trial. Dr. Hannon was immensely underqualified in any measurable way (experience, education, publications, academic appointments) to contradict Dr. Fleming at trial. *Id.* at ¶¶ 18, 36.e., 41. All of Dr. Harkonen's defense team, including Dr. Harkonen and Winchell, shared the opinion that Dr. Hannon was a weak expert witness who could be potentially called as a rebuttal witness to supplement Dr. Mayer's testimony, and that his weakness as a witness could work against Dr. Harkonen's defense. *Id.* at ¶¶ 41, 42.b., g. Once Dr. Mayer changed his opinion and could no longer be called as a defense witness, Dr. Hannon could not be used as the sole defense biostatistician expert against the government's expert Dr. Fleming. The defense team had met with Dr. Hannon several times. *Id.* at ¶ 18. This was not a case where defense counsel failed to investigate or contact a readily available witness. As deference is given to the decision-making process by defense counsel regarding which witnesses to call, particularly those that counsel has interviewed in person, Dr. Harkonen's claim that he was prejudiced by the failure to call Dr. Hannon is mere speculation. Trial counsel was in the best position to evaluate the strength of Dr. Hannon as a witness and balance the risks and benefits of calling him to testify at trial. *See Lord*, 184 F.3d at 1095.

iii. Dr. Goodman

Based on Dr. Harkonen's own filing, Dr. Goodman's opinions were not available to Topel and the rest of Dr. Harkonen's defense team. As part of Dr. Harkonen's request that the Court reconsider his motion for a new trial, filed on November 10, 2010, Dr. Harkonen stated that Dr. Goodman's declaration and his opinions were newly available, while acknowledging that the defense team had diligently sought appropriate defense experts before trial. Doc. 293 at 3-4.

Even assuming Dr. Goodman could have been available to testify to the opinions in his declarations in support of Dr. Harkonen at sentencing, none of those opinions undermine Dr. Harkonen's conviction.[13] The key biostatistician expert issue at trial was whether the press release was accurate in stating that the GIPF-001 clinical trial results alone showed a statistically significant survival benefit for IPF patients. Nothing in Dr. Goodman's declaration affirms the accuracy of the press release. Instead, Dr. Goodman states: "The government's claim that this non-significant result

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[13] Dr. Harkonen's Petition stated that the experts, such as Dr. Goodman, could have provided examples of two drugs, Carvedilol and Remodulin, that received FDA approval based on data "little different from that generated by the GIPF-001 trial." Doc. 399-1 at 33. The results from the clinical trials for Remodulin and Carvedilol were not at all similar to the results for the GIPF-001 clinical trial.

The p-value for survival for the Carvedilol clinical trial was 0.000008, whereas the p-value for survival was 0.084 for Actimmune. Fleming Dec. at ¶ 26. Dr. Fleming noted: "Carvedilol analyses and the GIPF-001 press release . . . [are] classic illustrations of the opposite ends of the spectrum regarding interpretation of survival data." *Id.* at ¶ 27. The totality of the Carvedilol "data supports a conclusion of benefit," whereas for the GIPF-001 clinical trial, "at best, the totality of the data supports the conduct of a confirmatory trial," which InterMune did and resulted in the failed GIPF-007 clinical trial. *Id.* The drastic contrasts between the results of the two trials "punctuates the inadequacy of the survival data from GIPF-001 in providing reliable evidence of survival benefit from Actimmune." *Id.*at 26.

Remodulin had two identically designed clinical trials which gave similar results that reinforced each other, while the results from the GIPF-001 clinical trial were from one trial, and were internally inconsistent. For example, any possible survival benefit in the GIPF-001 clinical trial results was undercut by no improvement in lung function and more deaths for severe IPF patients taking Actimmune versus placebo in the same results. The p-values for the primary endpoint of the two trials and the pooled p-value combining the results of those two trials were 0.0064, 0.0607, and 0.0550, respectively. Center for Drug Evaluation and Research ("CDER"), *Statistical Review and Evaluation: NDA # 21-272* at 8 (Oct. 16, 2000), attached as Exhibit 7. Additionally, when combining the Remodulin trials' primary endpoint, six-minute walking distance, with a secondary endpoint that also measured the ability to exercise, the result was a p-value of 0.00000084. CDER Division of Cardio-Renal Drug Products, Memorandum regarding *NDA 21-272 (Remodulin)* at 1-2 (Jan. 24, 2002), attached as Exhibit 8. The GIPF-001 clinical trial drastically missed its primary endpoint, achieving a p-value of 0.52, and failed on all secondary endpoints.

proves the inefficacy of this medication, and therefore that any claim to the contrary is fraudulent (even with correct reporting of the data), is in direct contradiction to the argument made by the government in its brief filed in the *Matrixx* case." Goodman Supp. Dec. ¶ 5. This statement would not have helped Dr. Harkonen at trial because the government was not claiming that Actimmune did not have a survival benefit. Rather, the government proved at trial that Dr. Harkonen's press release, that stated the GIPF-001 clinical trial results demonstrated a statistically significant survival benefit, was false because the results were inconclusive.

Dr. Goodman's declaration should not be considered because as Dr. Harkonen even admits, it was not available at trial despite the diligent efforts of Dr. Harkonen's defense team. Even if the Court were to consider Dr. Goodman's declarations, Dr. Goodman fails to state that the press release was accurate or offer any actual evidence of Dr. Harkonen's innocence to the wire fraud charge. Therefore Dr. Harkonen was not prejudiced by his absence at trial.

iv. Dr. Rubin

Dr. Harkonen was not prejudiced by Dr. Rubin's absence at his trial because Dr. Rubin's declaration does not state that Dr. Harkonen's press release was accurate. Instead, Dr. Rubin stated the results of the GIPF-001 clinical trial "did not foreclose a reasonable conclusion that Actimmune did provide a survival benefit to IPF patients." Doc. 283 at ¶ 2. The press release states affirmatively that the GIPF-001 clinical trial showed a statistically significant survival benefit, that is, that the results proved a survival benefit. Dr. Rubin's statement simply means that the GIPF-001 clinical trial results did not disprove a survival benefit. Again, the government proved at trial that the GIPF-001 clinical trial results were inconclusive; they neither proved nor disproved a survival benefit. Dr. Rubin's opinion that the GIPF-001 clinical trial results did not disprove a survival benefit, while true, would not have helped Dr. Harkonen's defense.

Additionally, Dr. Harkonen admitted that the defense team was diligent in their search for experts, from indictment through trial. Doc. 293 at 4. Dr. Harkonen was not prejudiced by the defense team's failure to discover Dr. Rubin at trial, as their search for experts was thorough and widespread. Since Dr. Rubin's declaration does not support the accuracy of the press release in any way, Dr. Harkonen's was not prejudiced by not having Dr. Rubin as a witness at trial.

2. Dr. Harkonen Was Not Prejudiced by the Decision Not to Call Defense Pulmonologists.

Dr. Harkonen was not prejudiced by his trial team's decision not to call an expert pulmonologist at trial, or to present the Doctor Tapes cited in the Petition. Defense pulmonologist testimony posed immense risks to Dr. Harkonen's defense, while offering little benefit. *See* discussion *supra* Argument Section III.C.2. Additionally, the statements on the Doctor Tapes cited in the Petition were hearsay evidence, and Dr. Harkonen could not be prejudiced by the defense team's failure to introduce inadmissible evidence at trial. Fed. R. Evid. 802. Nor could he be prejudiced by the failure to call witnesses who were not willing to support Dr. Harkonen's defense.

i. Dr. Zibrak

Dr. Harkonen was not prejudiced by the decision not to have Dr. Zibrak testify at trial. As discussed above, *see* discussion *supra* Argument Section III.C.2., based on the testimony that had come out through the government's case-in-chief, there was little value in defense expert pulmonologist testimony. *See* Topel Decl. at ¶ 33. While there was little benefit, there were immense risks to Dr. Harkonen's defense in having a defense pulmonologist cross-examined at trial, including the risk that the GIPF-007 clinical trial results would have been admitted at trial. *Id.* at ¶ 24.

Dr. Zibrak's declarations for Dr. Harkonen's sentencing make it clear that Dr. Harkonen was not prejudiced by the decision not to call Dr. Zibrak to testify at trial, and in fact that the trial team's decision was the prudent choice. Dr. Zibrak was aware of the disastrous GIPF-007 clinical trial results. Doc. 284 at ¶ 30. ("I was disappointed when I learned the negative outcome of the INSPIRE trial."). If Dr. Zibrak testified that he believed Actimmune helped IPF patients, this testimony could very well have allowed the government to cross-examine him with the GIPF-007 clinical trial results. He could also be cross-examined with his declaration, in which he stated he did not currently prescribe Actimmune for IPF. Doc. 284 at ¶ 7. Dr. Zibrak also stated that insurers became "reluctant to reimburse patients for prescriptions of [Actimmune] (which, at roughly $50,000 to $60,000 per year, is a very expensive drug)." *Id.* Furthermore, he directly refuted Dr. Harkonen's claim in the press release that the GIPF-001 clinical trial results demonstrated Actimmune's efficacy for treating the IPF disease. Dr. Zibrak stated: "I did not believe the . . .

GIPF-001 clinical trial, conclusively proved the efficacy of [Actimmune] for IPF." Doc. 317 at ¶ 15. With all of this harmful testimony possible from Dr. Zibrak, it is more than likely that his testimony would have harmed Dr. Harkonen's defense at trial. Therefore, there was no prejudice to Dr. Harkonen from not calling Dr. Zibrak at trial.

ii. Dr. Maxfield

Similar to Dr. Zibrak, Dr. Harkonen was not prejudiced by the decision not to call Dr. Maxfield testify at trial. Dr. Maxfield's testimony would have posed the same risks as Dr. Zibrak's testimony, and had the same limited value. *See* discussion *supra* Argument Section III.C.2. As with Dr. Zibrak, Dr. Harkonen's trial team made the prudent decision not to call Dr. Maxfield to testify.

iii. ERS Conference Pulmonologists

Even ignoring the evidentiary issue of whether the Doctor Tapes are admissible, Dr. Harkonen was not prejudiced by his counsel's decision not to use Doctor Tapes.

As discussed above, *see supra* Argument Section III.E.1., Dr. Noble's statements at the ERS conference did not support the statements in the press release and actually criticized the FVC cut-off used in the press release, making the ERS Tapes were harmful to Dr. Harkonen's defense. Coupled with Dr. Noble's refusal to assist Dr. Harkonen's defense or serve as a defense witness at trial, Dr. Harkonen's trial team's decision to forego using the ERS Tapes did not prejudice Dr. Harkonen.

iv. CHEST Pulmonologists

As discussed above, *see supra* Argument Section III.E.2., none of the statements from the CHEST conference tapes support the press release's overstatement of the GIPF-001 clinical trial results. On the contrary, several of them contradict the press release by stating the ambiguity of the results and the uncertainty as to whether there was a survival benefit.

Consequently, Dr. Harkonen was not prejudiced by the decision not to present statements from the CHEST tapes that ranged from irrelevant to harmful. This is especially so when the doctors were not willing to assist Dr. Harkonen's defense.

v. Dr. Nathan Tape

As discussed above, *see supra* Argument Section III.E.3., Dr. Nathan makes statements in his presentation about the inconclusive nature of the GIPF-001 clinical trial results which contradict the

false definitive statements in the press release.

Given Dr. Nathan's negative and accurate statements about the GIPF-001 clinical trial results on his tape, the decision by Dr. Harkonen's trial team not to use this tape did not prejudice Dr. Harkonen.

3. Dr. Harkonen Was Not Prejudiced by the Decision Not to Call Other Experts.

As discussed earlier, the only other two experts who were potentially relevant to Dr. Harkonen's defense and whom the defense team was able to retain after a lengthy and thorough search were Dr. Zunich and Dr. Katz. Dr. Harkonen was not prejudiced by the defense team's decisions not to call these witnesses because their testimony would not have helped Dr. Harkonen's defense.

i. Dr. Zunich

The government did not dispute at trial that the GIPF-001 clinical trial was well designed and run, so Dr. Zunich's testimony that the GIPF-001 clinical trial was well-designed and conducted was of no value. Topel Decl. at ¶ 36.c.; *see* discussion *supra* Argument Section III.C.3.i. Dr. Harkonen could not have been prejudiced by the decision not to call a witness to testify about undisputed facts.

ii. Dr. Katz

The defense team planned to use Dr. Katz to explain to the jury in simpler terms Dr. Mayer's interpretation of the GIPF-001 clinical trial results. Topel Decl. at ¶ 36.d.; Argument Section III.C.3.ii. Once Dr. Mayer was no longer a viable witness, it was no longer possible to call Dr. Katz to testify about the GIPF-001 clinical trial results, as Dr. Katz was not a biostatistician or pulmonologist; nor did he treat patients with IPF. Topel Decl. at ¶ 42.e.

Dr. Harkonen was not prejudiced by the defense team's decision not to call Dr. Katz as a witness at trial, as Dr. Katz lacked the required expertise to testify on his own about the GIPF-001 clinical trial results and the press release's characterization of those results.

C. Dr. Harkonen's Press Release is Not Entitled to First Amendment Protection Because the First Amendment Does Not Protect Fraudulent Speech.

The Supreme Court has repeatedly and unequivocally held that the First Amendment "does not shield fraud." *Illinois ex rel.Madigan v. Telemarketing Assocs., Inc.*, 538 U.S. 600, 612, 620

(2003) (elements such as scienter and materiality provide the requisite breathing room for speech that is in fact protected); *see San Antonio Cmty. Hosp. v. So. California Dist. Council of Carpenters*, 125 F.3d 1230, 1239 (9th Cir. 1997) ("The First Amendment does not protect fraud."). A statement does not need to be "literally false" to be fraudulent, but can be fraudulent if "misleading or deceptive." *United States v. Woods*, 335 F.3d 993, 998 (9th Cir. 2003). Even half-truths can be fraudulent. *See United States v. Sloan*, 492 F.3d 884, 889 (7th Cir. 2007) (scheme to defraud includes "'half truths that the defendant knows are misleading") (citing *Emery v. American General Finance, Inc.*, 71 F.3d 1343, 1346 (7th Cir. 1995)).

Since Dr. Harkonen's press release was fraudulent, it is not subject to any heightened First Amendment scrutiny. *Telemarketing Assocs., Inc.*, 538 US. at 612. Even assuming arguendo that the press release was not "literally false," the press release was at least "misleading or deceptive" and not subject to any heightened First Amendment protections. *Woods*, 335 F.3d at 998. Heightened scrutiny is not applicable to Dr. Harkonen's press release because his press release represents a deceptive opinion, not just a difference of opinions. *See id.*

Dr. Harkonen argues in his Petition that he was prejudiced by his trial team's failure to call an expert because under the First Amendment, defense expert testimony that the press release was accurate would have entitled him to an acquittal under the law. In support of his argument, Dr. Harkonen cites cases which he argues hold that he can be convicted of fraud only if *all* experts agree his statements in the press release were false. Doc. 399-1 at 63 (*emphasis added*). Dr. Harkonen's argument is contrary to the well-settled law that even true but misleading statements can support a fraud conviction. *Woods*, 335 F.3d at 998. This is the same argument that the Ninth Circuit rejected in Dr. Harkonen's direct appeal of his conviction. *United States v. Harkonen*, No. 11-10242, slip op. at 3 (9th Cir. Mar. 4, 2013).

Under the First Amendment, the jury may find the facts necessary to convict a defendant of fraud. *Cf. United States v. Keyser*, 704 F.3d 631, 638 n.1 (9th Cir. 2012) ("defer to the jury's findings on historical facts [and] credibility determinations"). Dr. Harkonen's jury was also entitled to find that the press release was fraudulent even if Dr. Harkonen called a witness to testify that the press release was not fraudulent. Conflicting evidence on the fraudulent nature of the press release

does not deprive the jury of the ability to find that the press release was fraudulent. *See Research Labs v. United States*, 167 F.2d 410, 414-17 (9th Cir. 1948) (jury permitted to weigh conflicting scientific testimony to determine whether statements describing a drug's efficacy are misleading).

Once a jury convicts a defendant of fraud, and a reviewing court determines that the jury found the facts that establish the defendant committed fraud, the First Amendment no longer applies. *See United States v. Stewart*, 420 F.3d 1007, 1019 (court affirms verdict where evidence was sufficient to support the jury's conviction for making false statements). Contrary to Dr. Harkonen's argument, the First Amendment does not raise the level of prejudice that he might have suffered from his trial team's decision not to call an expert to testify about the accuracy of the press release. Simply proffering some expert to testify that the press release was accurate would not have entitled Dr. Harkonen to an acquittal as a matter of law under the First Amendment. Rather the jury could have accepted or rejected any defense expert's opinion on the accuracy of the press release as it is entitled to do as the finder of fact. *See Research Labs.*, 167 F.2d at 414-17. Therefore, this Court's analysis of any potential prejudice to Dr. Harkonen from his trial team's decision to forego calling an expert is unaffected by the First Amendment.

D. *Matrixx* Does Not Apply Because Dr. Harkonen Took Statistically Insignificant Data and Stated the Data Was Significant.

Dr. Harkonen's Petition argues that the government's position in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), as well as the Supreme Court's decision in that case, are contrary to the government's prosecution of him. Dr. Harkonen misreads *Matrixx* as it is irrelevant to this case. Dr. Harkonen raised this issue before the District Court in a new trial motion and in his appeal to the Ninth Circuit. Both courts rejected his argument.

In *Matrixx*, the Supreme Court held: "A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events. . . . [M]edical experts rely on other evidence to establish an inference of causation. . . . [C]ourts frequently permit expert testimony on causation based on evidence other than statistical significance." 131 S.Ct. at 1319.

Dr. Harkonen was convicted of falsely stating that the GIPF-001 clinical trial results, which

were in reality ambiguous, inconclusive, and statistically insignificant, showed that Actimmune had a statistically significant survival benefit for IPF patients. The government's position in *Matrixx* and the *Matrixx* decision itself state that experts can use statistically insignificant data and other information to infer a link between a drug and an effect in patients. *Id.* Neither the government nor the *Matrixx* decision stated that it is permissible to falsely state that statistically insignificant data are significant as Dr. Harkonen did in his press release.

In rejecting Dr. Harkonen's earlier *Matrixx* attack on his conviction, the District Court stated: (1) "[Matrixx] does not mean that statistically insignificant data, on its own, provides a proper basis for substantiating the purported benefits of a drug[;]" (2) "If [Dr.] Harkonen had a good faith basis for concluding that Actimmune was an effective treatment for IPF based on a number of factors outside the GIPF-001 clinical trial results, he could have made those connections in the press release and this would be a very different case[;]" and (3) "[Dr.] Harkonen tries to recast the issue in this case as whether there was a good faith reason to believe that Actimmune in fact conferred survival benefits, but the question squarely presented is whether the August 2002 press release misrepresented the results of the GIPF-001 clinical trial in a material way." Doc. 369 at 15-16.

Similarly, the Ninth Circuit rejected Dr. Harkonen's *Matrixx* argument, stating: *Matrixx* "does not undermine the thrust of the government's theory in Harkonen's case. Harkonen's scientific methods were not on trial; the issue was whether he misleadingly presented his analyses in the Press Release." *United States v. Harkonen*, No. 11-10242, slip op. at 9 (9th Cir. Mar. 4, 2013)

As the District Court and the Ninth Circuit held, *Matrixx* is irrelevant to this case. This Court should reject Dr. Harkonen's third attempt to attack his conviction with *Matrixx*.

E. Prejudice Conclusion

Because the testimony through which its absence the Petition alleges Dr. Harkonen was prejudiced was either irrelevant to Dr. Harkonen's defense, more harmful than helpful to Dr. Harkonen's defense, or was unavailable to Dr. Harkonen (e.g., the physicians from the tapes were contacted by trial counsel and unwilling to act as defense witnesses and were even hostile to Dr. Harkonen's defense), Dr. Harkonen was not prejudiced.

Contrary to Dr. Harkonen's contention that he was undermined by trial counsel's failure to

present certain testimony at trial, Dr. Harkonen's defense was undermined by Dr. Harkonen's decision to take ambiguous clinical trial results and state they conclusively demonstrated Actimmune had a survival benefit for the IPF disease. With unfavorable facts and a lack of scientific support for Dr. Harkonen's position, trial counsel proceeded to defend Dr. Harkonen in the best way they could; Topel and Moorman elicited facts that could have led the jury to find Dr. Harkonen innocent on specific elements of the charged wire fraud, or at least find reasonable doubt as to his guilt. *See supra* Facts Section III.B.3.

Conversely to Dr. Harkonen's contentions in the Petition, counsel's decision not to call experts, with Dr. Harkonen's knowledge and consent, did the opposite of undermine his defense. Because of the beneficial testimony that was elicited by Topel and Moorman on cross and direct, there was little left to be gained by calling defense experts, and the trial team knew that with any speculative gains came far greater risks.[14] Additionally, the Petition advances no reasonable argument that Dr. Harkonen should receive any relief either through heightened First Amendment scrutiny or because of the decision in *Matrixx*.

The Petition fails to provide any error by Dr. Harkonen's trial counsel that shows a substantial likelihood of a different result. *Harrington*, 131 S. Ct. at 791-92. As this Response has refuted the allegedly erroneous omissions by trial counsel, nothing has been alleged to show that Dr. Harkonen was "deprive[d] . . . of a fair trial, a trial whose result is reliable." *Strickland*, 466 U.S. at 687.

CONCLUSION

For the foregoing reasons, Dr. Harkonen's Petition should be denied.

[14] Had trial counsel called defense expert witnesses whose testimony posed far more risk than benefit, Dr. Harkonen would today be alleging he was undermined by that decision.

Dated: February 6, 2015

Respectfully Submitted:

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